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Ethical Compliance Framework for Blockchain-Enabled Tissue and Organ Transportation Systems

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Abstract
Blockchain technology has become a ground-breaking innovation to improve tissue and organ transportation (T/OT) systems' operational efficiency, transparency, traceability, security, and trustworthiness. However, its application in this critical domain necessitates a stringent commitment to fundamental ethical principles, including respect for autonomy, non-maleficence and beneficence, fairness, and privacy. This study explores how an ethical compliance framework should be designed for blockchain-enabled platforms in the context of T/OT, a process characterised by sensitive, multi-stakeholder data sharing. A significant contribution of this study is the development of an "Ethical Compliance Checklist," a foundational tool designed to guide the ethical evaluation and enhancement of blockchain platforms. Furthermore, the study presents a comprehensive end-to-end scenario to illustrate the practical applicability of the proposed framework in a real-world T/OT context, thereby enhancing conceptual clarity. This work lays a crucial foundation for the design and implementation of a novel blockchain framework specifically dedicated to addressing the unique ethical challenges of T/OT. The study underscores the potential for blockchain technology to deliver transparent, equitable, and ethically sound digital solutions in healthcare, fostering greater trustworthiness in these critical applications. As part of future work, the technical implementation and empirical evaluation of the proposed end-to-end scenario will be conducted to assess its practical feasibility and potential impact on ethical compliance in T/OT systems.

Keywords: *Ethics, trustworthiness, fairness, blockchain, tissue and organ transportation, ethics by design*

JEL Classifications: *O33, I18, L86*

1. Introduction

A crucial phase in the organ/tissue transplantation process is organ/tissue transportation (T/OT). This stage encompasses the period from the retrieval of a tissue/organ from a living or cadaveric donor, through its packaging and labelling under appropriate conditions, to its arrival at the transplant centre, where it is unpacked and prepared for transplantation. Given the distinct biological characteristics of different organs and tissues, specific transportation protocols are required for each case. The fundamental objective of this process is to ensure that the tissue/organ reaches its designated recipient in the shortest possible time while minimising trauma, maintaining the integrity of the organ, and adhering to principles of transparency, reliability, and evidence-based practice. Despite significant advancements in medical technology, the methodologies employed in T/OT remain outdated and inefficient, relying on rudimentary techniques [1].

Statistical data from organ transplantation organisations reveal a persistent gap between organ supply and demand. For instance, in Europe, approximately 6 new patients are added to transplant waiting lists every hour, while an average of 19 individuals die daily due to the unavailability of a suitable organ [2]. This stark reality underscores the urgency of ensuring that every donated tissue/organ is efficiently and promptly delivered to its recipient. However, the lack of technological advancements in tissue/organ supply chains results in suboptimal utilisation of available resources, exacerbating inequities in organ allocation and accessibility [3].

Medical authorities have established strict ischaemic time limits for each organ, distinguishing between warm ischaemia and cold ischaemia [4]. Cold ischaemia time, in particular, must be meticulously managed during transportation, as prolonged exposure significantly increases the risk of organ rejection. Moreover, several procedural factors introduce ethical concerns, including the accuracy of packaging and labelling procedures, the documentation of elapsed time, the maintenance of cold chain integrity, the potential exposure of the transport container to physical trauma, and unauthorised access to the tissue/organ during transit. Addressing these issues requires an ethically robust, evidence-based medical framework to ensure the security and efficacy of the T/OT.

Blockchain technology presents a promising avenue for enhancing the efficiency, transparency, traceability, security, and reliability of T/OT systems. As a decentralised and distributed ledger, blockchain facilitates secure and trust-based data exchange without reliance on a central authority. However, its application in critical domains such as tissue/organ transportation necessitates strict adherence to fundamental ethical principles, including autonomy, non-maleficence, beneficence, fairness, and privacy. Ethics, in its broadest sense, is a branch of philosophy concerned with principles that define right and wrong, fairness and injustice, and moral responsibility. Ethical discourse is typically classified into three subfields: normative ethics, which focuses on moral principles and rules; metaethics, which examines the nature and logic of ethical concepts; and applied ethics, which provides practical guidance for ethical dilemmas in specific fields such as medicine, law, and engineering [5]. Medical ethics, in particular, revolves around ethical principles such as beneficence, non-maleficence, autonomy, fairness, and privacy, which are extensively articulated in key documents, including the Declaration of Helsinki, the Declaration of Geneva, and the Declaration of Lisbon on the Rights of the Patient [6–8].

This study explores the development of an ethical compliance framework for blockchain-enabled platforms in the context of the T/OT, a process characterised by highly sensitive, multi-stakeholder data exchange. The primary contribution of this research is the development of the Ethical Compliance Checklist – a novel evaluative tool designed to assess and guide the ethical considerations of blockchain-based T/OT systems. The remainder of this paper is structured as follows: Section 2 provides the Background; Section 3 details the development process of the Ethical Compliance Checklist; Section 4 introduces the characteristics of blockchain technology, highlights the necessity of a blockchain-based system in T/OT, and explains the role and technical architecture of blockchain through a comprehensive end-to-end scenario; and finally, the Conclusion and Future Work section summarises the findings and outlines prospective research directions.

2. Background

Recent studies on the tissue and organ transplantation supply chain have primarily focused on improving the efficiency of logistical processes. Most research in the literature centres around the question of how to transport an organ or tissue from point A to point B in the fastest and most cost-effective manner. Within this context, cold chain time constraints have been considered a fundamental parameter in logistics planning, with various strategies proposed to minimise transportation durations.

Stahl et al. [9] investigated the impact of the distance between donor and recipient on the success probability of organ transplantation. Their study demonstrated that increasing the distance negatively affects transplant success rates. Similarly, Cole [3] highlighted the inefficiencies of existing technologies in the organ supply chain, which prevent optimal utilisation of available organs. This study examined the integration of supply chain management practices into organ transplantation procedures in the United States and emphasised their potential to increase organ availability. However, it was also noted that these technologies might exacerbate existing inequalities in access to treatment, prioritising patients who are already in more advantageous positions within the organ distribution system. The author underscored the need for a fair and inclusive approach to organ allocation, advocating for logistics networks that are not solely driven by speed and efficiency but also designed to establish an equitable system.

Savaşer et al. [10] analysed the organ transplantation supply chain in Turkey, developing mathematical models to optimise potential donor-recipient matches. Their study evaluated different transportation modes within the constraints of cold ischaemia time and proposed logistics models tailored to the dynamics of organ transplantation transport. Similarly, Bellotti and Francoso [11] conducted a national-level study in Brazil aimed at optimising organ transplant logistics. Their research led to the development of a database that detailed the coordination between donors, recipients, and medical teams while considering ischaemia time and relevant regulations. The proposed system leveraged open-source data, such as web-based mapping tools and search engines, to facilitate efficient organ transportation. The study highlighted that while ground transportation was the primary mode, multimodal transport combinations were also employed when necessary. The developed system functions as a decision-support mechanism in organ transplant logistics.

Moreover, Salimian and Mousavi [12] explored the impact of environmental factors, such as climate change and supply uncertainties, on the organ transplantation supply chain. Their study proposed a scenario-based decision-support system that minimises organ degradation while optimising blood-type compatibility. The model assessed the influence of donor hospital locations, transportation modes, and weather conditions on allocation decisions. Adaptable to multi-organ transplant systems, this framework aimed to enhance cost and time efficiency in organ transplantation processes. Simulation results indicated that the proposed system improved organ quality by 17.8%.

A common theme across these studies is the focus on optimising logistics in organ transplantation, offering solutions that enhance speed, cost-effectiveness, and time sensitivity. However, there remains a gap in the literature regarding how these processes can be aligned with ethical principles, how sensitive data can be securely shared, and how equitable distribution among stakeholders can be ensured [13–17]. Addressing these gaps, the present study aims to develop an ethical compliance framework for blockchain-supported platforms in organ transplantation, characterised by sensitive and multi-stakeholder data sharing. In this context, an Ethical Compliance Checklist is proposed to enhance justice, transparency, and accountability in organ transplantation processes.

3. Development of the Ethical Compliance Checklist

The development of the Ethical Compliance Checklist was initiated by detailing the workflow of tissue/organ transportation. Subsequently, fundamental ethical criteria were identified to establish an ethical framework. Based on these principles, the proposed Ethical Compliance Checklist was formulated.

3.1. Tissue/Organ Transportation Workflow

The tissue/organ transportation process encompasses the transfer of a tissue or organ from a living or deceased donor to a recipient. The key stakeholders involved in this process include the donor and their legal representatives, the recipient and their legal representatives, the transport container, the tissue/organ extraction team, the transplantation team, and the logistics and transportation team. The organ or tissue is securely stored in a transport container from the moment it is retrieved from the donor until it is transplanted into the recipient.

The tissue/organ extraction team consists of medical professionals responsible for the removal of the organ or tissue, ensuring the accuracy of the procedure and adherence to ethical standards. The transplantation team comprises medical professionals who receive and transplant the organ into the recipient. The logistics and transportation team is responsible for the secure transfer of the organ and monitoring conditions such as cold chain integrity and trauma risk throughout the transportation process. Medical professionals oversee each stage of the transport process to ensure proper documentation, packaging, and transfer procedures (Figure 1).

The workflow diagram in Figure 1 illustrates the sequential stages involved in the transportation of tissues and organs from a donor to a recipient. This structured workflow ensures compliance with ethical, legal, and medical standards while maintaining organ viability throughout the process. During the extraction phase, essential information such as the authorised team's credentials verification, donor consent verification, brain death verification (for the deceased donor), warm ischaemia time, and operation details are recorded to ensure traceability and compliance with ethical guidelines [2, 18]. The Packaging stage involves securing the organ in accordance with preservation protocols, including the initiation of cold ischaemia and proper sealing of the transport container [4]. In the Transport phase, strict monitoring of cold chain integrity, trauma risks, and unauthorised access is maintained, with timestamping to enhance accountability and security [19]. Upon arrival at the transplantation site, the Unpacking stage ensures that the organ is handled properly, tracking unpacking time, recipient status, and the termination of cold ischaemia. Finally, the Evidence-Based Transport Tracking phase systematically records all relevant transport conditions, including storage temperatures, ischaemia times, and any potential damage or rejection incidents, ensuring process transparency and compliance with established regulatory frameworks such as the World Health Organisation (WHO) guidelines and the General Data Protection Regulation (GDPR) regulations [20, 21].

3.2. Defining the Ethical Framework

Although no single document codifies all European values and norms, the fundamental approach of the European Union (EU) is based on empowering individuals and protecting them from harm. The ethical principles relevant to blockchain-based systems include Security, Equality and Non-Discrimination, Justice and Fairness, Diversity and Inclusion, Privacy, Sustainability, Responsibility and Accountability, Freedom, and Ownership. Conversely, the fundamental characteristics of blockchain technology include Decentralisation, Immutability, Transparency and Distribution, Auditability, and Accountability. These features can influence how societies interact, and the design of such systems inherently reflects the normative perspective of the architect or developer. Therefore, ethical guidelines for blockchain-based systems are essential [22, 23].

In this context, the guidelines proposed by the Expert Group on Blockchain Ethics (EGBE) outline five core ethical principles for blockchain systems: Ensure Fairness, Protect Privacy, Assure Security, Allow for Accountability, and

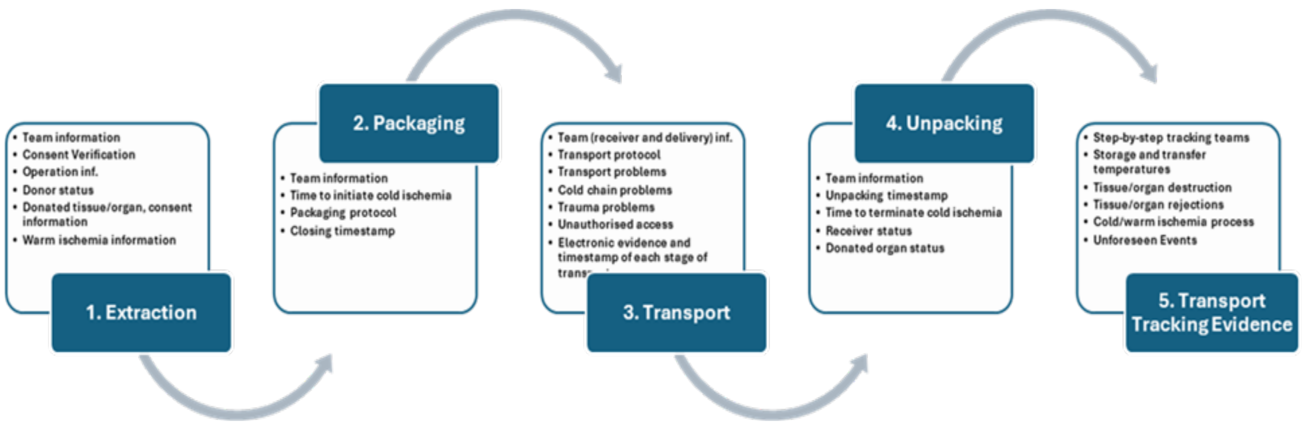

Figure 1. Tissue/organ transportation pathway.

Guarantee Societal Responsibility [24]. This study focuses on a specific application – tissue/organ transplantation – and is grounded in medical ethics principles.

All medical procedures, including organ transplantation – recognised as the only life-saving treatment for end-stage organ failure – must be conducted in alignment with ethical principles that safeguard individuals' fundamental rights, freedoms, and dignity. The Oviedo Convention emphasises the primacy of human well-being in medical applications, reinforcing the principle of informed consent, prohibiting genetic discrimination, and ensuring the protection of private life [18]. Additionally, supplementary protocols concerning the transplantation of human organs and tissues provide legal protections for both donors and recipients while regulating measures to prevent organ trafficking [25].

The WHO emphasises that tissue and organ donation should be entirely voluntary and free from financial incentives [20]. The Declaration of Istanbul highlights the exploitative nature of organ trafficking, particularly among socioeconomically disadvantaged individuals, and underscores the health risks associated with illegal transplants [19]. Furthermore, data protection regulations such as the GDPR [21] and the Health Insurance Portability and Accountability Act (HIPAA) [26] provide critical frameworks for safeguarding sensitive medical data. GDPR enhances patient privacy by granting individuals greater control over their personal data, whereas HIPAA imposes data security obligations on healthcare providers to prevent unauthorised disclosures. Additionally, the Council of Europe's National Transplant Organisation (NTO) guidelines aim to uphold quality and traceability standards while preventing unethical practices in organ and tissue transplantation [27].

Ethics, as a philosophical discipline, is generally categorised into three main schools of thought: Utilitarian Ethics, Responsibility Ethics, and Virtue Ethics. Utilitarian ethics evaluate actions based on their capacity to generate the greatest benefit, while responsibility ethics emphasise the ethical obligations of individuals and institutions. Virtue ethics, on the other hand, prioritises moral character and universal ethical principles. Ethical evaluations in healthcare predominantly follow the virtue ethics perspective, as decisions in this domain directly impact human lives. Ethics is not a static concept but rather a dynamic and continuously evolving framework. Social, technological, and economic developments constantly reshape and redefine ethical perspectives. In this context, ethics provides a guiding framework for effective decision-making in addressing emerging challenges [28]. Given the inherent characteristics of blockchain technology, it holds significant potential in supporting ethical principles in organ transportation processes. Specifically, blockchain's transparency, immutability, decentralised verification, and accountable trust offer key advantages for ensuring data security, process transparency, and ethical accountability in organ transplantation.

This study examines the ethical dilemmas associated with T/OT through the lens of medical ethics. The following describes the ethical dilemmas associated with each phase of T/OT.

- **Extraction Phase:** The donor consent presents several ethical challenges. For living donors, concerns about autonomy and the potential for coercion are significant. In the case of deceased donors, there may be ethical conflicts when families object to organ retrieval despite consent from the donor prior to death. When multiple organs are to be extracted, prioritising which organs to remove first also raises ethical dilemmas regarding fairness and allocation. In addition, whether an authorised team removes the tissue/organ with no conflict of interest also causes ethical dilemmas.

- **Packaging Phase:** The ethical implications of proper packaging and accurate documentation are critical in ensuring accountability in the organ transplantation process. Mistakes in packaging, delays in initiating cold ischaemia, or failures in maintaining proper records can directly affect the viability of the organ. In this phase, ethical concerns about responsibility and accountability for such errors are essential, with mechanisms needed to ensure that any failures are addressed transparently.

- **Transport Phase:** The transportation of organs introduces a range of ethical issues, including the prioritisation of recipients, maintenance of cold chain integrity, and the risk of unauthorised access. Ethical decisions must be made regarding which patients should receive organs first, especially in multi-organ transportation. Additionally, disruptions in the temperature control system that can affect organ quality present both medical and ethical challenges. There are also concerns about negligence or intentional interference during transport, which could result in organ damage or loss, raising serious ethical questions about accountability.

- **Unpacking Phase:** Upon arrival at the transplant site, ethical challenges regarding the verification and handling of the organ come to the forefront. This phase involves ensuring that the organ's condition is properly assessed, and that the recipient's data is accurate. Timely termination of cold ischaemia and correct documentation are vital for ensuring that the organ is fit for transplantation. If discrepancies in records or signs of organ damage arise, determining who is responsible and ensuring full transparency becomes ethically necessary. Ethical dilemmas also emerge if the recipient's condition has changed, requiring a decision on whether to proceed with the transplant or to reallocate the organ. This decision must weigh medical feasibility against fairness and ethical considerations.

- **Transport Tracking Evidence Phase:** Ethical considerations in the transport tracking phase focus on ensuring data security, traceability, and the integrity of records. Using decentralised systems like blockchain to store donor and recipient data increases security but also raises concerns about privacy. Maintaining comprehensive, transparent records is critical to preventing unethical practices, and guidelines must be in place to address issues like organ damage or rejection that could arise during transport. Ensuring that all records are kept accurate and secure is essential to maintaining ethical standards throughout the entire process.

3.3. Proposed Ethical Compliance Checklist

The adoption of the "Ethics by Design" approach by developers is the most critical starting criterion. This approach involves integrating ethical principles into the design phase of a product, system, or process. It provides a proactive method for preventing ethical violations and fostering responsible technology development. Traditionally, ethical issues are often identified and addressed only after a system has been developed and deployed. However, in this study, the "Ethics by Design" approach is employed to address these issues at the outset, aiming to minimise ethical breaches.

Blockchain technology has the potential to enhance the security of healthcare data. However, if not designed with ethical considerations in mind, it may lead to privacy violations. In this context, the "Ethics by Design" approach has been utilised to establish the fundamental ethical framework of medical ethics principles and the T/OT process. The core framework of the approach adopted in this study is presented in Figure 2.

Figure 2 presents the fundamental ethical principles guiding data governance in T/OT. The principle of autonomy emphasises respect for the control that donors, recipients, and their legal representatives have over their data, ensuring informed consent, data portability, and the right to be forgotten. Non-maleficence focuses on preventing harm resulting from data misuse during the transport process by implementing measures to avoid data breaches, mitigate algorithmic harm, and prevent psychological or social harm. Beneficence aims to maximise the benefits of data utilisation in T/OT by ensuring the positive impact of data use and the detection and mitigation of biases. Fairness underscores the importance of equitable data usage by eliminating discrimination in data processing, ensuring equitable access to data, and promoting transparency and accountability. Lastly, privacy safeguards the sensitive and personal information of donors, recipients, and legal representatives through data minimisation, anonymisation and encryption, secure storage and access controls, and compliance with relevant legal and regulatory frameworks. These principles establish an ethical foundation for data governance in T/OT, fostering trustworthiness and security in the process.

The Ethical Compliance Checklist consists of three sections. The first section defines the preliminary assumptions for blockchain-based T/OT systems (Table 1-a.). The second section identifies potential ethical dilemmas within the T/OT workflow (Table 1-b.). The final section integrates ethical principles with the specified use case (Table 1-c.).

Table 1-a presents a checklist of necessary ethical and technical assessments to be conducted in the early stages of blockchain-based T/OT systems. This checklist advocates for the adoption of the "Ethics by Design" approach, ensures the security of sensitive medical data, and requires decisions regarding the blockchain technology to be used and the manner in which data will be stored. Additionally, it addresses key technical aspects, such as the determination of which operations will utilise smart contracts, how data accuracy will be verified, and how integration with existing systems will be achieved. This framework emphasises the prior analysis of ethical risks and dilemmas.

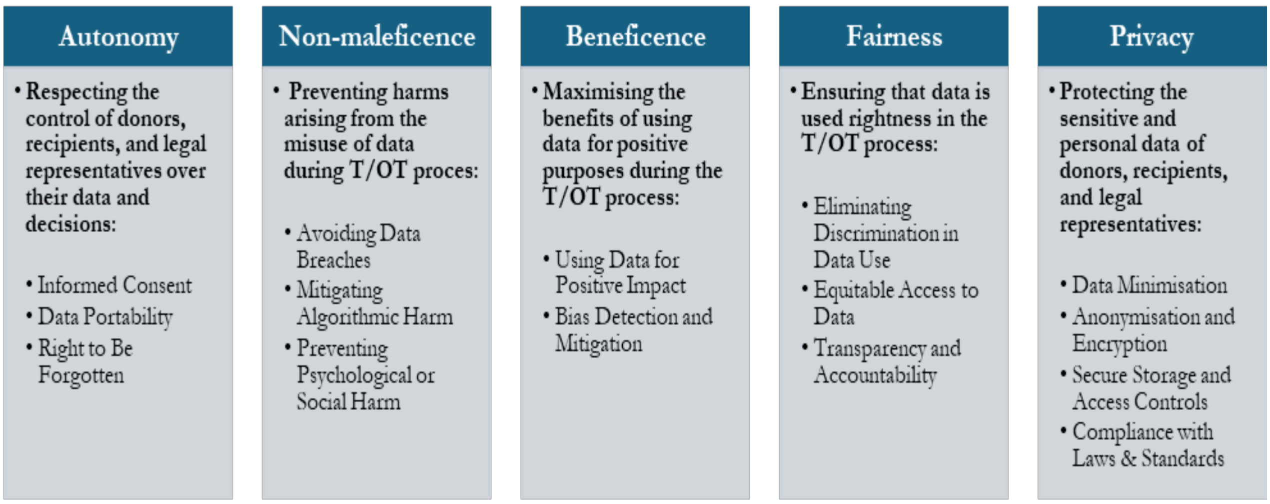

Figure 2. Key ethical considerations and data governance in T/OT.

Table 1-a. Proposed Ethical Compliance Checklist (a. Ethical and Technical Preliminary Checklist for Blockchain-Based T/OT Systems)

a. Preliminary:	**Yes**	**No**	**Note**
Has the "Ethics by Design" approach been adopted by the developers?			
Have the medically sensitive personal data been identified?			
Has it been determined who will have the authorisation to access medically sensitive personal data?			
Has a decision been made regarding which data in the T/OT process will be stored on-chain and which will be stored off-chain, ensuring their privacy, security, and integrity?			
Has a decision been made regarding which blockchain technologies will be utilised?			
Has it been determined whether the chosen blockchain technology will be integrated with the currently used systems, and if so, which ones?			
Has it been decided which transactions and operations in the T/OT process will be executed via smart contracts?			
Has a mechanism been established to verify the accuracy of the data entered into the blockchain?			
Have the T/OT stages been analysed from the perspective of ethical dilemmas?			

Table 1-b. Proposed Ethical Compliance Checklist – Continue (b. Ethical and Procedural Checklist for T/OT Pathway and Potential Ethical Dilemmas)

b. T/OT pathway and points where ethical dilemmas may occur:	**Yes**	**No**	**Note**
1. Extraction (Organ/Tissue Retrieval)			
Have the donor's identity and medical history been verified?			
Does the donor have explicit and informed consent for organ/tissue donation?			
Is the condition of the donor's organ/tissue suitable for transplantation?			
Has the donor's warm ischemia time been recorded?			
Are the necessary authorisation documents related to the donated organ/tissue complete (brain death, etc.)?			
2. Packaging			
Has the responsible team carried out the packaging process?			
Has the start time of the cold ischemia period been recorded?			
Has the packaging process been conducted in accordance with established protocols?			
Has the time spent on packaging been recorded?			
Has the closure time of the packaging been recorded with a timestamp?			
3. Transport/Shipping			
Have the identities of the transport team members been verified?			
Has the transport process been conducted in accordance with the designated protocols?			
Have any issues arisen during transportation?			
Have cold chain protocols been maintained without violations?			
Has any physical damage occurred to the organ/tissue container during transportation?			
Has there been any unauthorised access to the organ/tissue container?			
Has the identity of the team receiving the organ/tissue container been verified?			
Have all transport stages been electronically recorded with timestamps?			
4. Unpacking			
Has the unpacking process been carried out by the responsible team?			
Has the unpacking timestamp been recorded?			
Has the end time of the cold ischemia period been documented?			
Has the recipient's health status been confirmed as suitable for transplantation?			
Has the donated organ/tissue been verified as suitable for the surgical procedure?			
5. Transport Tracking Evidence			
Can the legality of the organ/tissue's origin be verified?			
Has every step of the transport process been recorded?			
Have the storage and transfer temperatures been properly documented?			
Has any damage or loss of the organ/tissue occurred?			
Has organ/tissue rejection taken place?			
Have the warm and cold ischemia processes been comprehensively monitored?			
Have any unexpected incidents been recorded?			

Table 1-c. Proposed Ethical Compliance Checklist – Continue (c. Key Medical Ethical Principles and Use Case)

c. Ethics Principles	**Yes**	**No**	**N**
1. Autonomy			
Has it been verified that informed consent has been obtained from the donor or their legal representative for organ/tissue donation?			
Have the donor, recipient, and legal representatives been granted full control over their data and decisions?			
Has data portability been ensured? (Can the data owner request their data?)			
Has the "right to be forgotten" been respected? (Can personal data be deleted when necessary?)			
2. Non-Maleficence			
Have adequate security measures been implemented to prevent data breaches during the organ/tissue transport process?			
Have algorithmic errors or biases in data usage been identified and corrected?			
Have measures been taken to prevent psychological or social harm during the organ/tissue transport process?			
Has the integrity of the cold chain been maintained throughout transportation?			
Has the organ/tissue transport process remained free from any physical damage?			
3. Beneficence			
Have the data been used solely for positive purposes in terms of health and safety during the organ and tissue			
Are the data analyses in the organ/tissue transport process applicable to medical benefits?			
Have the effects of data-related errors or incorrect decisions been minimised?			
Has the system been designed to proactively detect and prevent issues such as organ/tissue rejection, damage,			
4. Fairness			
Has discrimination and bias in data usage been prevented?			
Has a fair and impartial process been followed throughout the T/OT procedure?			
Are the T/OT processes equitable and inclusive? (Has no group been unfairly excluded?)			
Are the T/OT processes transparent?			
Are the T/OT processes accountable?			
5. Privacy			
Has the data been limited to only what is necessary? (Has unnecessary data collection been avoided?)			
Has the data been anonymised or encrypted? (Have appropriate methods been used to ensure privacy?)			
Have the necessary security measures been implemented for data storage?			
Has data leakage been prevented?			
Has data access been restricted to authorised personnel only?			
Have security measures been implemented to prevent the misuse of personal data?			
Has compliance with relevant local and international data protection laws and standards been ensured?			

Table 1-b identifies potential ethical dilemmas that may arise at various stages of the T/OT process. These stages encompass a wide range, from safeguarding the rights of both donors and recipients to ensuring the proper execution of procedures during transportation and packaging. Deficiencies in transparency, particularly in donor consent verification processes, can lead to ethical concerns. Additionally, privacy breaches and unauthorised access during the transportation, packaging, and storage of organs create ethical risks. The accuracy of timing and records, if compromised by manipulation or error, may result in ethical violations, while deficiencies in the medical evaluation of the tissue/organ and recipient suitability can lead to significant ethical issues. Moreover, shortcomings in traceability during the transportation and storage processes can raise ethical concerns regarding the quality and reliability of the organ.

Table 1-c outlines key ethical principles in the context of tissue/organ transport. Autonomy ensures informed consent from donors or their representatives, control over data, and respect for data portability and the right to be forgotten. Non-maleficence emphasises safeguarding against data breaches, correcting algorithmic errors, and preventing harm, including maintaining cold chain integrity and preventing physical damage during transport. Beneficence focuses on using data for positive health outcomes, minimising errors, and designing systems to prevent tissue/organ rejection, damage, or loss. Fairness ensures that T/OT processes are conducted equitably and transparently by preventing discrimination and bias in data usage, maintaining impartiality, promoting inclusivity, and upholding accountability throughout the procedure. Privacy mandates data minimisation, encryption, restricted access, and compliance with relevant data protection laws. These principles ensure the design by ethics throughout the transport process.

4. Blockchain Technology

Blockchain technology came to the fore with its successful application, namely Bitcoin, in 2008, and it still exists as an electronic currency. Blockchain is essentially a technology in which all peers in the system establish trust within the framework of the employed consensus mechanism, without the need for a central authority, thereby eliminating the necessity of a trusted third party. Transactions are converted into cryptographic data and stored in a tamper-resistant manner in a distributed ledger, which can be accessed by all parties or only by authorised participants, depending on the type of chain used (permissionless/public, permissioned/private, hybrid, or consortium). The content of each block generally includes metadata such as the hash value of the previous block, timestamp, and block number, along with the proposed transaction. Transparency, decentralisation, immutability, and security are among the key characteristics of blockchain technology. With decentralisation, the need for a trusted third party is replaced by trust in other peers within the network. This trust is established through consensus mechanisms. The most well-known of these include Proof-of-Work (PoW), Proof-of-Stake (PoS), Practical Byzantine Fault Tolerance (PBFT), and Proof-of-Authority (PoA), among others. With decentralisation, a peer-to-peer (P2P) structure is created in which every node in the network has equal authority. Since a record of all transactions on the chain is held by each peer, the system is inherently transparent and accountable, as historical transactions can be easily queried. Moreover, because transactions are encrypted and stored as cryptographic data on the blockchain, external access is highly restricted, making it a secure system. Once a transaction is added to the blockchain in the form of a block, it becomes immutable, meaning it can never be altered – thus ensuring a tamper-proof structure [29–31]. Traditional database architecture, by contrast, is based on a client–server model and relies on centralised authorisation mechanisms. In these systems, data can be modified, data integrity is verified before transactions are executed, and only the current data processed within a specific time frame is stored. The data processing workflow includes create, read, update, and delete (CRUD) functions, while data encryption is an optional feature. Transparency is achieved through analytical processing [32]. On the other hand, blockchain architecture features a P2P structure and utilises a decentralised authorisation model [33]. In blockchain, data cannot be altered; instead, data integrity is ensured by validating transactions prior to their addition to the ledger. Furthermore, all historical data is stored chronologically, from inception to the present. Data processing is limited to read and write operations only, and data encryption is a mandatory and integral part of the system. Due to its inherent design, blockchain naturally provides transparency and security.

4.1. Blockchain Suitability in T/OT

In healthcare, accurately identifying the technological requirements for any given process is of paramount importance. Equally critical is selecting the most appropriate technology to meet those requirements. As outlined in Section 3.2, ethical challenges associated with each stage of T/OT arise from inherent limitations of traditional systems – namely, lack of transparency, vulnerability to manipulation, and restricted accountability. This raises a fundamental question: Is blockchain technology genuinely necessary to overcome these systemic flaws? Several evaluation models have been developed to assess the suitability and applicability of blockchain in different contexts. For instance, Lo et al. [34] approached the question from a database design perspective, though their model did not comprehensively address aspects such as privacy or consensus mechanisms. Wüst and Gervais [35] proposed a decision model that classifies actors based on their trust level – trusted or untrusted – and uses this classification to assess the necessity and appropriate type of blockchain. However, their model does not sufficiently incorporate performance requirements. More recently, Monrat et al. [36] reviewed existing evaluation frameworks and introduced an "applicability analysis" guide that helps determine under which conditions blockchain should be used, whether a permissioned or permissionless model is suitable, and which consensus mechanism is most appropriate.

The use case addressed in this study emerges from the inability of conventional systems to ensure tamper-proof ethical medical evidence in T/OT workflows. When critical proof – such as verified consent or compliance with medical handling protocols – must be both immutable and verifiable without compromising privacy, the use of zero-knowledge-based cryptographic proofs stored on-chain becomes essential. These proofs enable public auditability while safeguarding sensitive details, aligning with the privacy and security requirements inherent in healthcare. Such capabilities are uniquely offered by blockchain's technical architecture and intrinsic properties. The proposed solution utilises a permissioned blockchain framework such as Hyperledger Fabric, which is particularly well-suited to T/OT scenarios involving trusted entities (e.g., surgical teams, hospitals, transplant coordinators, logistics providers, and regulators). Unlike public blockchains such as Ethereum or Bitcoin, permissioned blockchains limit access to authorised participants, ensuring compliance with data protection regulations such as GDPR and HIPAA.

Traditional databases are inherently vulnerable to manipulation, potentially leading to fraud or critical errors. For example, current systems cannot reliably and transparently verify whether a tissue/organ was packed under safe conditions, as manual tagging methods are still widely used. In contrast, blockchain guarantees immutability through its write-once-read-many structure and consensus mechanisms, enabling full transparency, traceability, and accountability. Furthermore, smart contracts can automate critical validations – such as confirming that an organ is transported within its safe temperature range. If deviations occur, the system can trigger alerts or halt the process, thereby preventing potential harm to the recipient. Unlike centralised databases controlled by a single authority, blockchain's distributed nature reduces the risk of mismanagement or abuse in organ allocation and

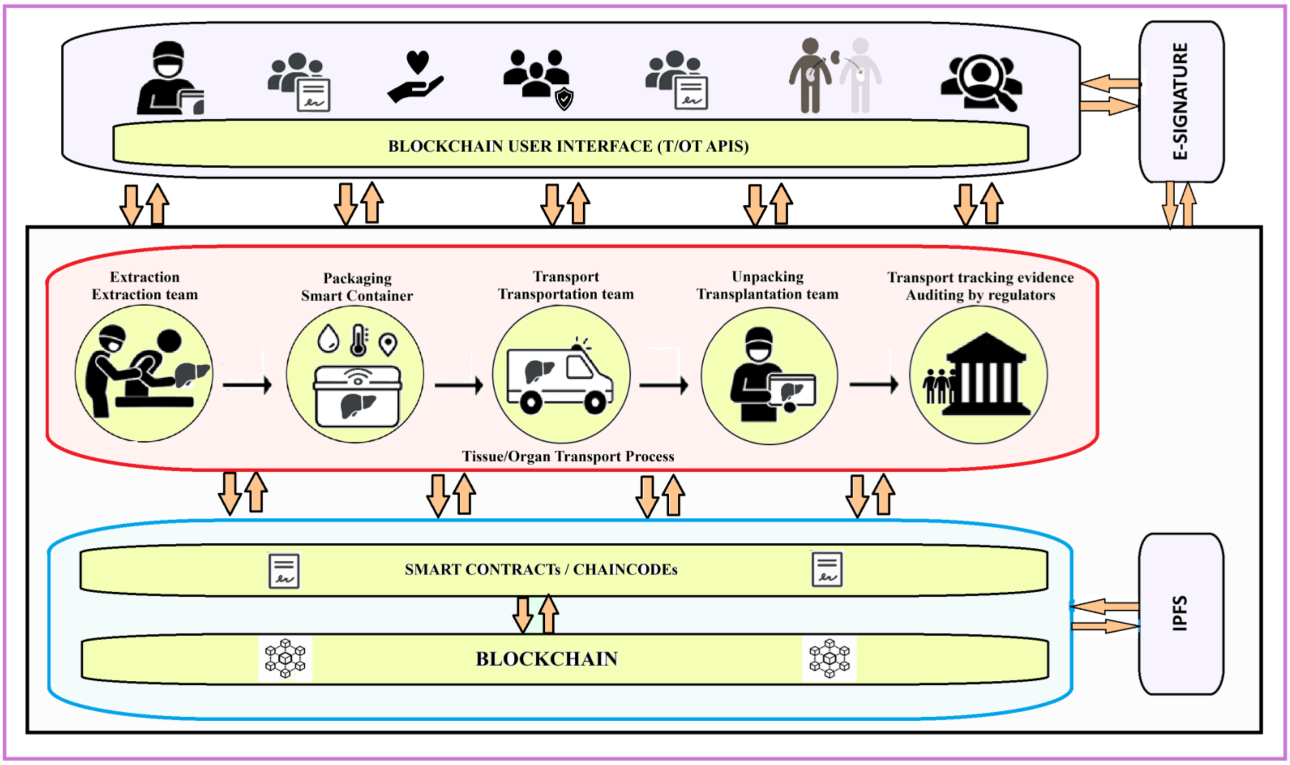

Figure 3. The general architecture of an end-to-end integration scenario: blockchain's role in T/OT.

transport. Ultimately, this ensures that scarce medical resources like tissues and organs are used in the most efficient, fair, and ethically sound manner.

4.2. Blockchain Integration in T/OT

In this regard, to provide a concrete real-world scenario, an end-to-end integration example illustrating blockchain's role in T/OT is outlined as follows (Figure 3).

• The general architecture of end-to-end integration scenarios includes Application Programming Interfaces (APIs) that enable stakeholders to interact with the blockchain-backed platform. During the transport of tissue or organs from the organ extraction centre to the organ transplantation centre, the solution ensures that each stage of the process complies with established ethical standards and remains verifiable.

• A donor organ is extracted by the authorised surgical team. At this point, on-chain records are created to capture essential metadata – such as donor ID verification, consent validation, location data, and extraction timestamp – each hashed and immutably recorded using cryptographic techniques.

• To further strengthen data privacy while enabling on-chain validation, a Zero-Knowledge Proof (ZKP) approach is applied. This allows the system to prove that critical ethical and procedural conditions have been met – such as verifying that valid donor consent was obtained or that the transplant team is properly authorised – without revealing the actual consent document or personal credentials. By doing so, the system ensures transparency and accountability without compromising sensitive information.

• To safeguard sensitive operational data while maintaining transparency, an off-chain storage mechanism using the InterPlanetary File System (IPFS) is implemented. For example, encrypted files containing the verified transport route and the authenticated credentials of medical and logistics personnel involved in the organ handover are uploaded to IPFS. Only their unique content identifiers (CIDs) are stored on-chain, enabling verifiable linkage without exposing sensitive data. This design ensures both GDPR/HIPAA compliance and auditability.

• The organ is then placed in a smart transport container equipped with IoT sensors (e.g., GPS, temperature, humidity, gyroscope, and accelerometer). These devices collect and transmit real-time environmental and positional data, which is logged on-chain in an encrypted format to ensure tamper-proof traceability.

• During transportation, smart contracts continuously monitor sensor data. If any condition exceeds safe thresholds – such as internal container temperature falling outside the +2°C to +8°C range, or an accelerometer registering above 3.0 g – an on-chain event is triggered. This notifies the medical team and pauses the process. For instance, if a sudden impact is detected (e.g., mishandling or collision), the system automatically halts further progress until the situation is reviewed. Medical personnel must then verify that ethical preconditions, such as the organ's safety and continued viability, are still satisfied before resuming transport.

• Upon arrival at the transplant centre, the authorised medical team digitally signs a receipt confirmation using secure e-signature protocols integrated with their verified blockchain identities. This confirmation is automatically recorded on-chain as a permanent and auditable proof of delivery and handover. This ensures that only verified and authorised personnel can finalise the receipt process, strengthening accountability and traceability at this critical stage of the transport chain.

• Finally, regulators are granted read-access permissions to the system. This allows authorised bodies to audit the entire process – from extraction to transplant – by accessing the on-chain logs and IPFS-linked data, ensuring accountability and ethical compliance at all stages.

4.3. Ethical Enforcement

• **Autonomy:** Donors and recipients may access their personal data through a secure portal linked to the blockchain. Through this portal, they may exercise their "right to be forgotten" by requesting the deletion of their off-chain personal records from IPFS, while on-chain logs preserve only anonymised hashes.

• **Non-maleficence:** The system proactively logs and flags any deviation from the acceptable transport parameters (e.g., temperature fluctuations, impact levels). This ensures that no potential harm to the organ goes unnoticed.

• **Beneficence:** If the organ container is damaged or compromised, a smart contract immediately alerts medical personnel, preventing the use of a potentially non-viable organ and protecting the recipient from negative outcomes.

• **Fairness:** The immutable and transparent on-chain logs prevent tampering with the organ allocation process, ensuring fair and ethical distribution of organs across all stakeholders.

• **Privacy:** All sensitive data is encrypted and stored off-chain. Role-based access controls ensure that only authorised personnel can view identifiable information, maintaining confidentiality in line with privacy regulations.

1. Conclusion and Future Work

This study highlights the potential of blockchain technology in transforming tissue and organ transportation (T/OT) systems, emphasising its role in improving operational efficiency, transparency, traceability, security, and trustworthiness. Through the development of the Ethical Compliance Checklist, this work offers a structured approach to integrating ethical principles into the design and implementation of blockchain-based T/OT systems. By adhering to fundamental ethical values such as autonomy, non-maleficence, beneficence, fairness, and privacy, the proposed framework ensures that blockchain solutions can be developed with careful consideration of the unique challenges presented by the sensitive nature of healthcare data and the multi-stakeholder environment inherent in organ and tissue transport.

Integrating the "Ethics by Design" approach at the outset of the development process emerges as a crucial element in preventing ethical violations and ensuring that blockchain technology can be harnessed responsibly. Through proactive assessments, the Ethical Compliance Checklist supports the identification and resolution of potential ethical dilemmas at each stage of the T/OT pathway, from organ retrieval and packaging to transport and unpacking. Furthermore, the checklist ensures that blockchain applications are developed in alignment with ethical principles, thereby fostering greater trust among stakeholders and enhancing the overall integrity of the T/OT system.

Furthermore, the provided end-to-end integration example of a blockchain-based T/OT system implements a robust data governance framework that balances transparency, privacy, and ethical compliance. On-chain data – such as hashed donor metadata, consent validation, time-stamped events, digital signatures, and sensor-triggered alerts – is immutably recorded to ensure verifiability and accountability across the transport lifecycle. To preserve data confidentiality, ZKPs are employed, enabling the system to cryptographically prove that ethical and procedural requirements (e.g., donor consent and team authorisation) have been met without revealing sensitive documents. Meanwhile, operationally sensitive records – such as verified transport routes and team credentials – are encrypted and stored off-chain via the IPFS, with only CIDs referenced on-chain. Role-based access controls restrict data visibility to authorised personnel, and stakeholders such as donors and recipients are empowered to exercise their "right to be forgotten" by requesting the deletion of off-chain personal data. Furthermore, digital signatures linked to verified blockchain identities ensure that only authorised medical teams can confirm critical handovers. Regulatory bodies are granted read-only access for external audits, ensuring compliance with ethical standards and legal data protection requirements such as GDPR and HIPAA.

While this study contributes significantly to the understanding of ethical considerations in blockchain-enabled T/OT systems, several areas warrant further exploration. Future work could focus on refining the Ethical Compliance Checklist through empirical studies, testing its applicability and effectiveness in real-world settings. Additionally, the evolving nature of blockchain technology calls for ongoing analysis of emerging challenges and opportunities, particularly with respect to the scalability, interoperability, and regulatory compliance of blockchain platforms in the healthcare domain. It is essential to continue developing solutions that address not only the technical and ethical requirements of T/OT systems but also the broader social, legal, and cultural implications of their widespread adoption.

In conclusion, the proposed ethical compliance framework represents a critical first step towards integrating blockchain technology into T/OT systems while safeguarding ethical principles. By ensuring that the technological advancements in organ and tissue transportation are underpinned by robust ethical guidelines, this study sets the stage for the creation of more transparent, equitable, and secure healthcare systems that promote the well-being of all stakeholders involved in the organ donation and transplantation process. Future research should aim to enhance these frameworks, investigate new ethical challenges as the field evolves, and work towards the establishment of international standards that can guide blockchain applications in critical healthcare services. As part of our future work, the technical implementation and empirical evaluation of the proposed end-to-end scenario are provided to assess its practical feasibility and overall impact.

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The authors declare no conflicts of interest.

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