Multi-User Support in Pan-European Kidney Exchange Programs

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Abstract: This paper focuses on the requirements and implementation of multi-user support within the KEPsoft software, a platform designed to manage and optimize matching processes in national, international and pan-European kidney exchange programs. We analyze the organizational levels involved in KEPs – transplant centers, pools, and collaborations – and propose a graph-based model to represent their relationships. Building on this structure, we define role-based access control mechanisms tailored to the specific responsibilities of different user types, including clinicians, coordinators, administrators, and data protection officers. We present a detailed permission model aligned with organizational hierarchies and demonstrate how this supports both operational efficiency and compliance with regulatory standards such as GDPR and MDR. The proposed framework enables flexible and secure system use across multiple countries and institutions, supporting cross-border kidney exchange and promoting equitable access to transplantation.

Keywords: kidney exchange programs; KEP; multi-user support; role-based access control; GDPR; MDR

1 Introduction

End-stage renal disease is a severe medical condition that can be managed through dialysis; however, this treatment is associated with reduced quality of life and limited life expectancy. Kidney transplantation remains the only viable long-term solution. While deceased donor transplantation is an option, the demand for organs far exceeds the available supply, resulting in prolonged waiting times. Consequently, living kidney donation has become an increasingly preferred approach, offering superior graft survival rates compared to deceased donor transplantation.

Despite the advantages of living kidney donation, transplantation is not feasible when a patient has a willing but immunologically incompatible donor. To address this limitation, kidney exchange programs (KEPs) have been established in numerous countries to facilitate donor exchanges, thereby increasing transplant opportunities for patients with incompatible donors [1]. Various collaboration strategies can exist within centralized kidney exchange programs [2]. Some of the most extensive KEPs in Europe operate in the United Kingdom, the Netherlands, and Spain. In addition to national programs, three international KEPs are currently in operation in Europe. The European Union funded EURO-KEP project currently investigates and supports the birth of a pan-European level cooperation between a cluster of countries in Europe [3].

A recipient in KEP is a registered patient with end-stage kidney disease who requires a kidney transplant, but a direct donation from family or friends is impossible due to biological incompatibility. Donors are family members or close friends who offer one of their kidneys to be transplanted in the patients. A non-directed donor is an altruistic individual who donates a kidney without specifying a recipient. These donors often initiate transplant cycles and chains, enabling multiple incompatible donor-recipient pairs to receive compatible organs. Compatibility is the biological suitability between a donor and recipient that ensures the recipient's immune system does not reject the transplanted kidney. Key factors of compatibility are ABO blood type and HLA (Human Leukocyte Antigen). PRA (Panel Reactive Antibody) is a percentage indicating the proportion of HLA-incompatible donors from a given database due to the presence of HLA-antibodies a recipient has developed (due to prior transplants, pregnancies, or blood transfusions). Virtual compatibility is a preliminary compatibility estimation using donor/recipient HLA and ABO blood type data without physical testing, while laboratory compatibility is measured by laboratory crossmatch testing, where the recipient's serum against the donor's cells are tested to detect incompatibility.

Maximizing the effectiveness of KEPs necessitates an information system that efficiently manages recipient-donor data and optimizes transplant allocations. KEPsoft is an example for a specialized software designed to support kidney exchange programs (KEPs) by optimizing the matching process between donors and recipients [4]. It facilitates the identification of compatible donor-recipient pairs in both national and international exchange programs, improving the efficiency of kidney allocation. Within the KEP information system, implementing a robust user role and permission system is crucial for maintaining data security, privacy, and operational efficiency. The IT system should be designed to support various levels of access and control, reflecting the complex nature of organ donation and transplantation processes.

The objective of the paper is to give a clear overview of the requirements of multi-user support in pan-European KEPs. To achieve this goal we study the collaboration types in European KEPs and the place of pan-European cooperation in this framework, we describe the potential user types and their functions in KEPs, collect the requirements and give a recommendation for the implementation. The rest of the paper is organized as follows. Section 2 summarizes the necessary details of international KEP collaborations. Section 3 analyses the operational, technical, and regulatory aspects of multi-user support in Kidney Exchange Programs (KEPs)**,** covering how their information systems manage roles, permissions, security, and compliance (GDPR, MDR) to enable secure, scalable, and legally compliant collaboration among diverse stakeholders in cross-border organ exchanges. Section 4 describes the implementation framework for multi-user support in the KEPsoft system**,** detailing how Role-Based Access Control Structure's permissions, roles, and organizational levels to securely manage diverse stakeholder interactions.

2 Towards a Pan-European Kidney Exchange Program

The operational practices of European KEPs have been systematically analyzed by Biró et al. in [5], and the data and optimization requirements by Smeulders et al. in [6]. The development of kidney exchange programs in Europe began with the establishment of national programs, such as the Dutch Living Donor Kidney Exchange Program (2004), the UK's NHS Living Donor Kidney Sharing Scheme (2007), and the Spanish national program (2009). These programs demonstrated the effectiveness of pairing incompatible donor-recipient pairs within national borders, significantly increasing transplant opportunities. However, the limited size of national donor pools posed challenges, particularly for highly sensitized patients. This limitation led to the emergence of international collaborations. Currently, three international KEPs are operating in Europe such as the Czech-Austrian Kidney Exchange Program from 2016 [7] with recent expansion to include Israeli hospitals. STEP is coordinated by Scandiatransplant, the deceased organ-sharing organization serving Denmark, Finland, Iceland, Norway, Sweden, and Estonia [8]. KEPSAT, integrates the national kidney exchange programs of Spain, Italy, and Portugal [9].

The ENCKEP (European Network for Collaboration on Kidney Exchange Programmes) COST Action ran from 2016 to 2021 with the objective to create a European interdisciplinary network to analyze, harmonize, and improve kidney exchange programs, fostering collaboration and developing tools to support both national and international exchanges [10]. This COST Action developed a simulator programme to model kidney exchange scenarios across borders [11]. The KEPSOFT project (2022-2023), focused on creating advanced software tools for transnational kidney exchange programs [12], while the ongoing EURO-KEP project (2025-2027) seeks to support a unified pan-European KEP by further refining these tools [3]. The development of KEPsoft software through these initiatives provides a robust platform for managing international kidney exchanges, ensuring compatibility and efficiency in matching algorithms.

A pan-European KEP would operate on three levels: transplant center, pool, and collaboration. At transplant center level, individual hospitals would contribute donor-recipient pairs to national or regional pools. At pool level, countries or regions would manage their own exchanges while also contributing to a larger collaborative network. At collaboration level the international KEPs are coordinated, including also the future pan-European scheme that would facilitate cross-border matching, optimizing transplant opportunities for patients with complex compatibility profiles. The implementation of a pan-European KEP could significantly advance kidney transplantation in Europe by expanding equitable access to transplants and fostering deeper collaboration among member states.

We studied the currently existing KEPs in Europe and identified the various ways in which European transplant centers participate in them. Based on our findings, we distinguish two types of participation. In the first, which we call Scenario A, all transplant centers at national or regional level send information on all their recipients and donors to a centralized exchange – known as a pool – where a centralized matching process is conducted. For example, the Netherlands operates a national pool, while the STEP collaboration operates an international pool that follows this model.

In the second model, Scenario B, participation is organized across three levels. At the first level, transplant centers submit donor-recipient data to national pools (the second level), where an initial matching process may take place. At the third level, national pools forward their unmatched donor-recipient pairs to an international exchange for further matching opportunities. The KEPSAT initiative follows this model: matching is first performed at the national level, and only unmatched donor-recipient pairs are forwarded to the international exchange. A variation of this scenario could also involve no matching at the national level – only data forwarding – with all matching occurring at the international level.

In the future, the envisioned pan-European KEP is anticipated to operate under Scenario B. Initially, national matching processes would be conducted, followed by a second phase where unmatched donors and recipients could enter an existing centralized international exchange. In the third phase, any remaining unmatched pairs from national or international pools could be submitted to the pan-European exchange for additional matching opportunities. This multi-phase approach would be applicable to countries already participating in international collaborations. However, the second phase could be omitted, allowing for a direct transition from national matching processes to the pan-European KEP in the future.

An alternative future scenario for the pan-European KEP could involve bypassing national-level matching altogether, with national interests within pools safeguarded through mechanisms such as a credit system (as discussed in [14]), data governance frameworks, or outcome monitoring. In this setup, all matching would be conducted exclusively at the pan-European collaboration level.

At the transplant center level, individual hospitals or transplant centers register donor-recipient pairs into the kidney exchange system. These centers are responsible for collecting and maintaining detailed medical and immunological data, such as HLA typing and PRA levels, which are crucial for compatibility assessments. The transplant centers also coordinate the medical evaluation of donors and recipients and perform the transplants once a match is identified.

At the pool level, donor-recipient pairs from multiple transplant centers within a country or region are combined into a shared database. Regular matching processes are conducted on this database using advanced algorithms while ensuring adherence to local regulations. This approach creates a larger pool of potential matches, improving the likelihood of finding compatible donors for recipients. Pools are typically managed by national or regional organizations that oversee the matching process. For example, Spain operates a national pool, while STEP as an international KEP can also be considered a pool, as transplant centers submit their donor-recipient pairs directly into its centralized system.

The collaboration level involves cross-border cooperation between different national or regional pools. At this level, international kidney exchange networks, such as KEPSAT, facilitate matches across countries by integrating data from multiple national pools into a centralized system. This level requires harmonized legal frameworks, logistical coordination and standardized protocols to ensure seamless collaboration. The collaboration level significantly expands the donor pool, enabling matches for hard-to-match patients who might otherwise remain unmatched within their national systems. By integrating these three levels, international KEPs optimize the efficiency and equity of kidney allocation while addressing the challenges of compatibility and access.

To enable multi-user support within the information system for the KEP process, it is essential to accurately model the organizational structure of the KEP. We propose a graph-based structure, outlined in Fig. 1, where the vertices represent organizational units within the KEP. An organizational unit may be a transplant center, a pool, or a collaboration. These vertices are organized across three hierarchical levels: transplant centers at the first level, pools at the second, and collaborations at the third. Each transplant center is associated with (connected to) exactly one pool, while a pool belongs (is connected) to one or more collaborations. This approach reflects the expectation that the introduction of a pan-European KEP would not necessarily replace existing international collaborations; rather, these may continue to operate in parallel. This structure accurately reflects the organization of currently operating KEPs in Europe. In Fig. 1, Scenario A is indicated by dashed circles, while Scenario B is represented by a dotted circle.

Users of the system are associated with specific organizational units and perform their roles within these units. A user may belong to multiple organizational units. A user may belong to multiple transplant centers, but only to a single pool and to a single collaboration. If a user has multiple memberships across different hierarchical levels, these must follow a parent-child relationship within the graph. As shown in Fig. 1, a user may belong to Collab1, P1, and TC1 because Collab1 and P1, as well as P1 and TC1, are connected in the graph through a parent-child relationship. However, a user cannot simultaneously belong to only Collab1 and TC1 as they are not directly connected, nor can a user belong to multiple pools or multiple collaborations, such as Pool1 and Pool2 or Collab1 and Collab2.

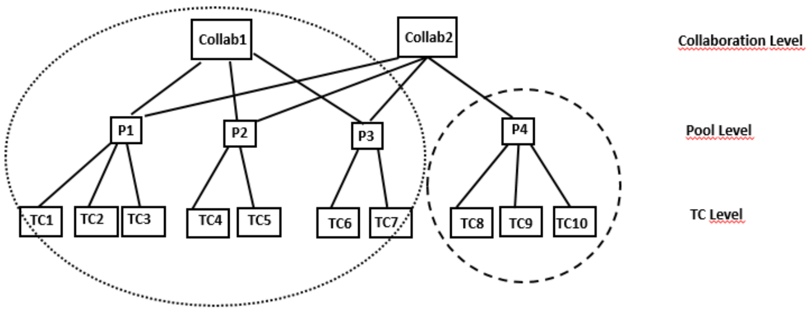

Figure 1
Scope of national and international KEPs

3 Operational Aspects of Multi-User Support in KEP

As outlined previously, the effective functioning of KEPs relies on a robust information system capable of managing donor-recipient data and facilitating exchange processes to optimize transplant allocations. This section delineates the essential concepts underpinning such information systems, analyzes potential user groups, summarizes the core functionalities of the operation, and reviews relevant regulatory frameworks that influence the design of multi-user support mechanisms. By addressing these components, the discussion provides a comprehensive foundation for understanding how information systems can meet the complex demands of multi-user support in cross-border kidney exchange initiatives.

A cycle is a sequence of donor-recipient pairs in which each donor in the cycle donates a kidney to the next recipient in the sequence, ultimately looping back, with the final donor giving to the first recipient. A chain is a sequence of donations initiated by a non-directed donor (someone donating without a paired recipient). Each subsequent donor in the chain donates to the next recipient, with the chain optionally ending in a donation to the deceased donor waiting list.

A compatibility graph is a directed graph representation of all potential matches in a KEP. Nodes represent the original (mostly incompatible) donor-recipient pairs or altruistic donors, and edges indicate biological compatibility (ABO/HLA compatibility,). Matching algorithms analyze this graph to identify cycles and chains.

The optimization policy defines the criteria used to prioritize matches during a match run. Common policies include maximizing transplant numbers or prioritizing highly sensitized patients. A match run is the process of executing a matching algorithm on the current pool of donor-recipient pairs to identify optimal cycles and chains. Match runs are conducted periodically (e.g. quarterly) and vary in scope (national or international). A solution refers to the final set of selected cycles and chains after a match run. It represents the optimal allocation of kidneys based on the program's optimization policy.

Primary users of this system include clinicians, immunologists, KEP coordinators, administrators, software service engineers and data protection officers, each fulfilling distinct but interdependent functions critical to the program's success. Each user is associated with at least one organizational unit, which can be a transplant center, a pool, or a collaboration.

Clinicians and immunologists serve as the frontline users, responsible for entering and validating recipient-donor data, including medical details such as HLA data, ABO blood type, sensitization levels (e.g., PRA scores), desensitization information, various personal data, constraints to potential donors (like age and BMI range or kidney placement). They might need to reject compatible pairs from proposed solutions due to logistical or medical constraints (e.g., geographic distance). KEP coordinators, often working at regional, national or international levels, set optimization policies, conduct match runs and review the results of each match run. They also retain the authority to reject compatible pairs from the solutions. Administrators play a pivotal role in managing user access and user roles. Software service engineers handle technical implementation, including system installation, algorithm updates, and integration with existing healthcare IT frameworks such as HLA tissue typing or Hospital Information System. They also onboard new organizational units (e.g., transplant centers or pools) by deploying initialization scripts to configure databases, define administrative roles, and establish foundational system parameters. Data protection officers ensure GDPR compliance by safeguarding patient rights, including transparent access to personal and medical data stored in the system.

To minimize security risks in KEP information systems, the principle of Least Privilege is critical: users receive only the minimum permissions necessary for their tasks, preventing unauthorized access or accidental data breaches. Complementing this, granular control enables fine-tuning of permissions within roles to address the unique requirements of specific KEPs, ensuring flexibility without compromising security.

The KEP information system must also prioritize scalability, enabling seamless addition of new roles and organisational units to the system, as collaborations expand across centers, regions, or countries. This adaptability is essential for evolving programs, particularly those engaging in cross-border organ exchange, where permissions must align with international data protection standards (e.g., GDPR) and accommodate varying regulatory landscapes.

Audit and logging mechanisms are indispensable for accountability, tracking sensitive actions like donor-recipient data modifications. Paired with regular reviews of user roles and permissions, these processes ensure continued appropriateness and security as organizational needs evolve.

Regulatory requirements profoundly shape the design and operation of KEP information systems. The General Data Protection Regulation (GDPR) mandates strict protocols for handling sensitive health data, requiring encryption, role-based access controls, and audit trails to protect donor and recipient privacy. Simultaneously, the EU Medical Device Regulation (MDR) (EU 2017/745) applies to software components classified as medical devices, necessitating rigorous validation, risk management, and documentation to ensure clinical safety and efficacy.

The GDPR uniformly regulates the protection of personal data of natural people across all member states of the European Union. On one hand, it imposes strict requirements on the processing of personal data; on the other hand, it facilitates the removal of barriers to the free flow of such data within the Union [15].

With regard to personal data processing, both the GDPR and the MDR articulate expectations that can be translated into information security requirements. Article 5 of the GDPR calls for the implementation of appropriate technical and organizational measures to ensure data security and protection ("integrity and confidentiality"). Similarly, MDR Article 23.4 mandates the definition of minimum requirements for medical devices that include or consist solely of software, explicitly emphasizing protection against "unauthorised access." These expectations are consistent with the risk-based approach also promoted by the MDR.

The *Guidance on Cybersecurity for medical devices* [16] outlines the cybersecurity-related requirements of the MDR and their relationship to other relevant EU legislation. Based on [16], Fig. 2 depicts the sources of regulatory security requirements for the development life cycle of the KEP information system, demonstrating that MDR compliance cannot be achieved without the effective management of IT and information security.

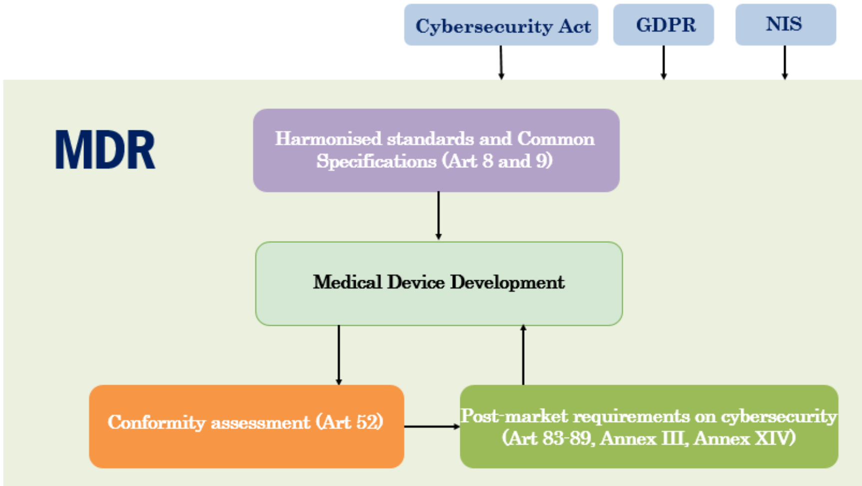

Figure 2
Sources of regulatory security requirements

In the context of the kidney exchange program, the IT system process sensitive health and genetic data of data subjects, which fall under the category of "sensitive data" and therefore require special attention. According to Article 9(4) of the GDPR, Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health [17]. This means that compliance for the KEPsoft software cannot rely solely on EU-level regulations, but must also consider national legal specifics in each country.

To ensure that meeting the varying requirements of different countries does not necessitate modifying the system's source code during access control, we have designed a flexibly configurable, role-based access control solution. Execution rights for various system activities can be assigned to roles, while users of the system are assigned one or more roles. Through careful design of the roles, the principles of purpose limitation and data minimisation [17] can be enforced, and by defining mutually exclusive roles, the Segregation of Duties information security principle can be fulfilled.

Article 15 of the GDPR states that data subjects have the right to access information regarding the processing of their personal data. Therefore, the system must be capable of logging data access events and, upon request, generating reports based on these logs. To support this, a general-purpose logging mechanism has been implemented within the system. It is capable of logging a wide range of events in formats that can later be processed and analyzed using various tools, such as ElasticSearch [18].

4 Implementation Framework of Multi-User Support

In this section, we present our solution for multi-user support in the KEPsoft program, designed to facilitate the operation of KEPs across multiple levels, including both pool- and collaboration-level exchanges. Effective multi-user support in KEPs requires a robust, secure, and adaptable framework to accommodate diverse stakeholders while ensuring compliance and operational efficiency. Central to this framework is Role-Based Access Control (RBAC), which assigns permissions to roles rather than individual users, streamlining management and maintaining consistency.

In our approach, user permissions in the program are defined once and remain stable over time, with each permission specified at the finest practical level of granularity. Every permission is tied to a single object and a single function related to that object. Additionally, each permission is explicitly linked to a specific organizational unit type – such as a transplant center, pool, or collaboration – meaning that the permission grants authority over instances of the object within that organizational scope. The relevant concepts and their relationships are summarized in Fig. 3 and Table I.

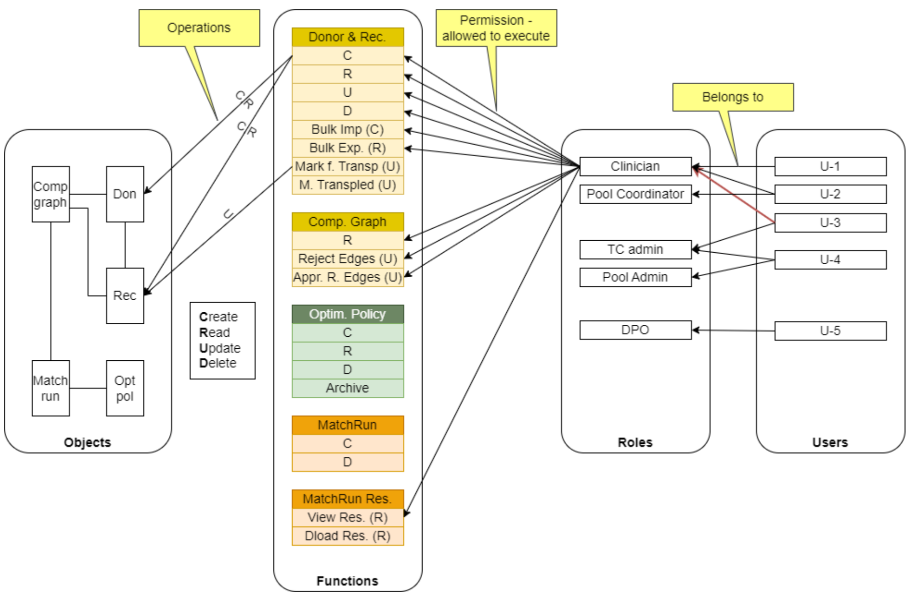

Figure 3
Role based access control in KEPsoft

Table 1
Permissions, Functions and Objects in KEPsoft

Object	Function	Unit	Name of the permission
Donor/Recipients	Create	TC	Create Donor Recipients
	Update	TC	Update Donor Recipients
	Read	TC	Read Donor Recipients
	Delete	TC	Delete Donor Recipients
	Bulk Import	TC	Bulk Import Donor Recipients
	Bulk Export	TC	Bulk Export Donor Recipients
	Mark All Selected For Transplant	Pool, Collab	Mark All Selected For Transplant
	Mark Pair Selected Transplanted	Pool, Collab	Mark Pair Selected Transplanted
Compatibility graph	Reject Edges From Matchrun	TC	Reject Edges From Matchrun
	Approve Remaining Edges From Matchrun	TC	Approve Remaining Edges From Matchrun
Optimization Policy	Create	Pool, Collab	Create Optimisation Policy
	Read	Pool, Collab	Read Optimisation Policy
	Delete	Pool, Collab	Delete Optimisation Policy
	Archive	Pool, Collab	Archive Optimisation Policy
Matchrun	Create	Pool, Collab	Create Matchrun
	Delete	Pool, Collab	Delete Matchrun
Matchrun Result	View Matchrun Result	TC, Pool, Collab	View Matchrun result
	Download Matchrun Result	Pool, Collab	Access Matchrun Excel

Within the KEPsoft program, the key objects relevant to permissions include donors and recipients, compatibility graphs, optimization policies, match runs, and match run results. The associated function defines the specific action that can be performed on the object. These actions include standard CRUD operations, data import/export via file upload, data archiving, or modification of particular attributes that are tightly coupled with the application's specialized functionalities.

Examples of these specialized functions include rejecting specific donor-recipient pairs within a match run, or updating the status of donors and recipients to values such as *Selected for transplant* or *Transplanted*. Permissions are enforced within KEPsoft by enabling or disabling corresponding UI elements, ensuring that only authorized users can perform the actions associated with their roles. The correctness of permission enforcement can be verified using test scripts that track operations executed on relevant database tables during specific test scenarios.

Roles are predefined sets of permissions, and a user is assigned one or more roles, gaining the associated permissions through these roles. Pool coordinator, pool administrator, transplant center administrator, clinician and data protection officer are existing roles probably in each KEP, but some roles can vary across different KEPs. If a new role is required in a KEP, it can simply be introduced by defining that role and assigning it the appropriate existing permissions. We distinguish between administrative users and business-level users, they are distinct set of individuals.

Each permission and role operates exclusively at one level – either transplant center, pool, or collaboration. Additionally, each user belongs to an organization (or in some cases, multiple organizations). For instance, the *CreateDonorRecipients* permission functions at the transplant center level because each donor and recipient is tied to a specific transplant center. On the other hand, permissions such as *RunningMatchrun* must operate at either pool or collaboration level, as they involve broader organizational scopes. This design ensures flexibility while maintaining clear boundaries for user roles and permissions within the system. This role-permission framework provides KEPsoft with the flexibility, scalability, and security needed to support diverse participants in both national and international kidney exchange collaborations.

Conclusions

As KEPs expand across national borders, the need for secure, flexible, and scalable information systems becomes increasingly critical. This paper addressed the requirements and implementation of multi-user support within such systems, focusing on the role-permission framework of the KEPsoft software. By analyzing the structure and operational logic of European KEPs and modeling their organizational hierarchy through a graph-based approach, we proposed a multi-level access control mechanism that ensures both operational clarity and regulatory compliance.

The proposed system distinguishes between organizational levels – transplant centers, pools, and collaborations – and aligns user roles and permissions accordingly. Through the use of role-based access control (RBAC), fine-grained permission definitions, and adherence to the principle of least privilege, our framework supports a wide range of user types, including clinicians, administrators, coordinators, and data protection officers. This design allows for precise control over sensitive operations such as donor-recipient data handling, match execution, and audit logging, while also enabling the system to adapt to diverse national and international contexts.

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