

# Pathways to equitable access to kidney transplantation in Spain (PATH2KT): A transformative mixed-methods study protocol

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## Abstract

**Introduction.** Chronic kidney disease (CKD) affects 10%–15% of the global population and is projected to become the fifth leading cause of years of life lost by 2040. Despite the benefits of kidney transplantation (KT), access remains inequitable. In Spain, which leads the world in KT rates per million population, disparities may persist due to structural, territorial, and professional barriers. This study aims to explore the mechanisms underlying treatment deprivation and inequity in KT access using a mixed-methods approach.

**Methods and analysis.** A transformative mixed-methods design will be implemented in four phases: (1) systematic reviews on instruments assessing treatment deprivation and inequalities in CKD and KT; (2) a multicentre quantitative study and qualitative interviews with professionals and patients; (3) a pre-experimental evaluation of a training program on KT; and (4) triangulation and translation of findings to inform national policy. The protocol adheres to GRAMMS and PRISMA guidelines.

**Ethics and dissemination.** Approved by the Hospital del Mar Research Institute Ethics Committee (ID: 2025/12128/I), the study complies with EU data protection laws. Informed consent will be obtained. Findings will be disseminated via peer-reviewed publications, conferences, social media, and patient forums to support equity-focused strategies in KT.

**Registration and financial details.** Registered on ClinicalTrials.gov (ID: XX); systematic reviews registered in PROSPERO. Funded by the Spanish Organización Nacional de Trasplantes (€74,597.49), with additional funding to be sought. Funders will not influence any part of the research process.

**Keywords.** Kidney transplantation; chronic kidney disease; Health equity; Treatment deprivation; Access to care; Social determinants of health; Mixed-methods research; Transformative paradigm

## **Strengths and limitations of this study**

- This is the first national study in Spain to examine treatment deprivation and access inequities to KT using a transformative mixed-methods design.
- It includes both professional and patient perspectives to understand the underlying mechanisms of inequity.
- The study will generate actionable evidence to inform national strategies, including the ATRAE initiative.
- The multicenter design enhances generalizability but may introduce variability in data collection processes.
- Although the study focuses on the Spanish context, findings may be applicable to other decentralized health systems facing similar challenges.

## INTRODUCTION

It is estimated that between 10% and 15% of the global population, approximately 850 million people, have some degree of chronic kidney disease (CKD), based on a global population of approximately 8.06 billion and recent estimates from the literature <sup>1-3</sup>. This figure is expected to rise, with 5.4 million people projected to undergo some form of renal replacement therapy (RRT) by 2030 <sup>4</sup>. Furthermore, CKD is expected to become the fifth leading cause of years of life lost worldwide by 2040 <sup>5</sup>. In light of these trends, it is also well-known that not all individuals who require RRT have access to it, and between 2.3 and 7.1 million adults die prematurely due to lack of access <sup>6</sup>. This situation should serve as a wake-up call for the international health community, who must firmly commit to implementing measures and equitable pathways across the global population, while also adopting preventive strategies to reverse the anticipated burden of disease in less than 10–20 years.

Among all RRT modalities, kidney transplantation (KT) offers the greatest benefits in terms of survival, complications, quality of life, and economic costs, making it the treatment of choice for this population <sup>7-9</sup>. However, access to KT remains limited, as it is available only to a portion of the global population <sup>10,11</sup>. As of the most recent data, KT activities were reported by 91 of the 193 countries worldwide, indicating that less than half of all countries currently provide or, at least, report this service <sup>12</sup>. This highlights persistent global disparities in access to transplantation. Barriers to treatment are influenced not only by a country's income level or healthcare infrastructure, but also by broader structural, geographic, and systemic challenges that go beyond the socioeconomic profile of a territory or its gross domestic product <sup>11</sup>.

Several studies have been published internationally, analyzing barriers to equitable access to KT. These studies describe factors such as race, gender, age, religion, comorbidities or accompanying disabilities, socioeconomic and educational level, place of residence, geographic distribution of health services, personal and professional characteristics of healthcare teams, staffing at reference centers, legislation, presence of other economic interests or preferences, and more, which significantly influence access – or lack thereof – to KT <sup>7,10,13-18</sup>. In the Spanish context, although universal healthcare coverage is in place, inequalities in access to KT might exist across different regions and patient profiles. These analyses are challenging to interpret collectively, due to the vast

number of individual determinants to consider and the discrepancies observed between studies, which are not always aligned <sup>10,14</sup>.

Given these challenges, over the past few decades, deprivation indices have been increasingly used under a health and evaluation framework in assessing access to healthcare. Deprivation indices are tools that quantify social, economic, and geographical inequalities limiting access to healthcare <sup>19</sup>. In the context of CKD, the preliminary use of these indices has shown that social deprivation is linked to a lower likelihood of receiving preventive KT or living donor transplants, worse clinical outcomes, and higher mortality rates <sup>20-23</sup>. In Spain, there is a lack of studies addressing how social and territorial inequalities impact access to KT, as well as a lack of comprehensive analyses exploring how personal, structural, and systemic variables interact to shape access to or deprivation from KT.

Focusing more specifically on the Spanish case, CKD affects an estimated 15% of the adult population, corresponding to approximately seven million people <sup>24</sup>. However, less than 1% progress to advanced stages of CKD requiring RRT, with around 65,000 individuals currently receiving dialysis or living with a functioning KT <sup>25</sup>. Among these, approximately 55% have received a transplant, underscoring Spain's internationally recognized leadership in KT activity. Nevertheless, a proportion of eligible patients may not ultimately access this treatment. As observed internationally, a local study in Southern Spain revealed that only a fraction of patients with advanced CKD are ultimately evaluated for KT, despite being the treatment with the most favorable outcomes at both personal and systemic levels <sup>17</sup>. In this regard, it is important to highlight that research on access to KT in Spain remains limited, and key hypotheses have yet to be empirically tested.

Building on this gap, the present study protocol is based on the hypothesis that treatment deprivation and inequities in access to KT may not be randomly distributed, but may result from the interaction of systemic, social, and professional factors embedded at different levels of the healthcare system. In line with this assumption, the protocol aims to explore the potential factors that may contribute to inequity and treatment deprivation among individuals with CKD in relation to KT access. Focusing exclusively on the Spanish healthcare system and sociopolitical context, it also seeks to examine how such factors may be structurally embedded in society and to explore the perspectives of professionals working in this field, with the aim of identifying possible areas for

improvement. Upon completion of the different stages of this protocol, we aim to outline a framework that could offer applicable responses for healthcare management systems, which may help inform the implementation of corrective measures to promote more equitable and high-quality care.

## **Objectives**

This project is divided into six specific objectives, which will be addressed in parallel to provide answers and, in the end, construct a unified meaning with all integrated parts:

1. To synthesize and critically appraise the literature on instruments and variables used to evaluate inequities among individuals with CKD.
2. To explore how unequal access to KT is portrayed and explained in the scientific literature.
3. Analyze possible inequities of access to KT in the CKD population in Spain, using a quantitative approach.
4. Explore the experiences of healthcare managers in Spain at the micro, meso and macro levels, as well as the experiences of patients, regarding health inequalities and access to KT, using a qualitative approach.
5. Evaluate the impact of a training course on living donor KT in Spain on the knowledge, attitudes, and practices of nurses and physicians by comparing indicators before and after the training.
6. Triangulate and translate the study's findings into actionable evidence to inform the national strategy for equitable access to KT in Spain, particularly by supporting the development of consensus recommendations within the ATRAE initiative.

## **METHODS AND ANALYSIS**

### **Study design**

The design of this research protocol follows the premises of the mixed-methods approach under the transformative paradigm <sup>26,27</sup>. This means that various phases of data collection –both quantitative and qualitative– will be conducted, analyzed separately, and then integrated through methodological triangulation to corroborate and enrich the findings <sup>28</sup>. The research will be centered on social justice, amplifying the voices of communities facing health inequalities or treatment deprivation. Using the transformative mixed-methods approach, different power structures that may be involved in the results will be

analyzed and linked to actions that promote equity, ultimately providing a report with recommendations for action based on the results obtained <sup>26,27</sup>. The achievement of results under this methodology and paradigm will be accomplished through various research phases, explained in detail below.

This protocol follows the Good Reporting of A Mixed Methods Study (GRAMMS) guidelines, recognized for ensuring high-quality evidence-based methodology <sup>29</sup>.

### **Patient and public involvement**

This protocol has been reviewed and endorsed by the CKD community in Spain, including the National Federation of Associations for the Fight Against Kidney Diseases (ALCER) and the ADER Foundation (Kidney Patients Association of Catalonia). These organizations will actively support the dissemination of the study in different regions and will facilitate recruitment of participants during the data collection phase. Moreover, patient representatives will be involved in the interpretation of findings, ensuring that the analysis incorporates lived experiences and enhances the relevance and clarity of results.

### **Study setting and context**

The data collection components of this research protocol will be conducted in Spain, a high-interest setting for the care of people with CKD. Spain's healthcare system is public and universal, primarily funded through taxes, ensuring healthcare access for the entire population, including individuals requiring KT <sup>30</sup>. The country is internationally recognized for its high rates of organ donation and transplantation, supported by the Spanish National Transplant Organization (Organización Nacional de Trasplantes, ONT), which emphasizes coordination, regulation, and public engagement <sup>31</sup>. Spain's healthcare system is also highly decentralized, with responsibilities for healthcare planning, service delivery, and resource allocation delegated to the 17 autonomous regions. This structure includes regional transplant coordination offices that work in alignment with the ONT to implement national policies at the local level, but may also reflect regional specificities and priorities. Despite this strong institutional framework, inequities in KT access might arise from factors such as socioeconomic status, geographic area and interregional differences linked to the decentralized organization of the healthcare system. By focusing solely on the Spanish context, while allowing for international discussion across the proposed phases, this study seeks to generate detailed insights and propose actionable

recommendations grounded in the realities of Spain's healthcare infrastructure and sociopolitical landscape.

## **Data collection and analysis**

Data collection and analysis will be carried out using a mixed approach, combining both quantitative and qualitative methods. This will result in four distinct research phases, tailored to the specific objectives of this research protocol.

### ***Phase 1. Literature review***

The first phase of this study aims to address objectives 1 and 2, which focus on synthesizing and critically appraising the existing literature on instruments and variables used to evaluate inequities among individuals with CKD, as well as on examining how unequal access to KT is described and explained. To achieve this, two systematic reviews will be conducted.

Both reviews will be carried out following the methodological recommendations of the Joanna Briggs Institute (JBI) and will be reported according to the PRISMA 2020 guidelines<sup>32,33</sup>. The protocols for the reviews will be registered in PROSPERO®. Searches will be conducted in the major electronic databases, using controlled vocabulary (MeSH) and will include peer-reviewed studies published between 2015 and 2025 in English, Spanish, French, or Portuguese. Eligibility criteria will be based on the PICOT framework, and include quantitative, qualitative, and mixed-methods research, as well as systematic and scoping reviews. Study selection, data extraction, and critical appraisal will be carried out independently by two or more reviewers, with discrepancies resolved by consensus or consultation with a third reviewer. Covidence® software will be used to manage the workflow.

Given the expected methodological heterogeneity, results will be synthesized narratively and organized thematically, according to the domains assessed, levels of analysis, validation approaches, and applicability of the instruments in both clinical and research contexts. These findings will provide a foundational knowledge base for the subsequent phases of the study.



## ***Phase 2. Inequities analysis***

This phase addresses objectives 3 and 4 by examining inequities in access to KT among individuals with CKD.

For the quantitative component (objective 3), a descriptive study will be conducted across Spain using a snowball sampling strategy through healthcare networks and patient organizations to ensure representativeness and inclusivity. Recruitment will continue until data saturation is reached, with a minimum of 500 participants to guarantee diversity across sociodemographic groups. Data will be collected through the questionnaires developed in Phase 1, complemented with sociodemographic and clinical variables to provide a comprehensive understanding of participants' health status and backgrounds. A multi-channel strategy will be applied to facilitate recruitment, involving healthcare professionals at nephrology and transplant centers, national and regional patient associations such as ALCER and ADER, and an online standardized interest form disseminated through institutional and collaborative networks, including ONT, SEDEN, and SEN. All participants will receive an information sheet and will be able to contact the research team directly to confirm their participation. No clinical information will be accessed without explicit consent, and contact details will only be shared if the participant initiates communication. This decentralized approach ensures voluntary participation and strict compliance with ethical standards in research involving potentially vulnerable populations. Statistical analysis will be carried out using SPSS® software. Descriptive statistics, including means, medians, standard deviations, and frequencies, will be used to summarize the sample characteristics, while inferential analyses such as t-tests, Wilcoxon tests, chi-square tests, and regression models will be applied depending on the type and distribution of the data. Assumptions for parametric tests will be verified, with non-parametric alternatives used when appropriate. Missing data will be managed through multiple imputation or complete-case analysis, depending on the extent and pattern of missingness, in order to ensure the robustness and validity of the findings.

For the qualitative component (objective 4), a descriptive study with a phenomenological orientation will be conducted to explore and understand in depth the experiences, perceptions, and meanings attributed to treatment deprivation by both healthcare professionals and individuals living with CKD. This approach will enable the identification of common patterns and differences between perspectives, providing a comprehensive view of the phenomenon from both sides of the healthcare relationship.

Data will be collected through semi-structured, in-depth interviews guided by open-ended, non-directive questions designed to foster a fluid dialogue between interviewer and participant. Two main groups of participants will be included: healthcare professionals involved in CKD care and KT, and patients with direct experience in the transplant process, including evaluation, waiting list, or transplantation. Healthcare professionals must have at least two years of experience in nephrology, transplant coordination, or related fields. Participants will be selected using purposive sampling with maximum variation to ensure diversity in roles, stages of CKD, and geographic regions. Interviews will be conducted by trained researchers or research assistants experienced in qualitative interviewing and working with vulnerable populations. Sessions will take place either in private spaces at participating healthcare centers (e.g., hospitals, transplant units, nursing schools) or through secure video calls, according to participants' preferences and availability, ensuring accessibility. Each interview is expected to last between 45 and 60 minutes, will be audio-recorded with prior consent, and subsequently transcribed verbatim for analysis. Follow-up interviews will be scheduled if necessary. Recruitment will continue until theoretical saturation is reached, defined as the point where no new themes or categories emerge from additional data <sup>34</sup>. Data will be analyzed inductively using a thematic approach and content analysis to identify and categorize recurring patterns, with successive steps of coding, grouping into categories, and synthesizing into central themes. To ensure credibility and rigor, strategies such as investigator triangulation, participant validation, and reflective journaling of analytical decisions will be applied <sup>35</sup>. All data will be anonymized using unique codes, stored securely, and handled in compliance with ethical standards. Atlas.ti software will be used to support the analytic process.

Upon completing this second research phase, we will have detailed data on inequities in access to KT in the Spanish context, together with the meanings attributed to this phenomenon by both the professional community and patients, providing comprehensive insights to inform the subsequent phases of the study.

### ***Phase 3. Impact of training***

In this third phase, objective 5 will be addressed by evaluating the impact of a training course in Spain on living donor KT for healthcare professionals. This particular course has been selected due to its established relevance within the Spanish context and potential

impact upon access to KT: it has already completed three successful editions and has gained national recognition as one of the most important and well-regarded training programs on KT in Spain. Notably, the course is aimed at professionals working in non-transplant centers, particularly dialysis units and advanced CKD clinics, which positions it to directly influence early referral pathways and improve access to KT. Its consolidated presence and perceived influence on clinical practice make it a strategic candidate for evaluation.

A preexperimental quantitative study will be conducted with a pretest-posttest design. The study population will consist of healthcare professionals participating in the training, selected through convenience sampling. Data collection will be carried out through a structured questionnaire that will measure participants' knowledge, attitudes, and practices before, after, and one year after the course. The questionnaire will include multiple-choice questions to assess knowledge, Likert scales to analyze attitudes, and questions about behaviors and clinical decision-making regarding living donor KT. The instrument's validity and reliability will be verified through prior piloting and consensus among the research team. Data analysis will involve descriptive statistics to characterize the sample and compare pre- and post-intervention results. Statistical tests such as the paired t-test or the Wilcoxon test, depending on the data distribution, will be applied to determine whether significant differences exist after training. Additionally, effect size measures, such as Cohen's *d* for continuous variables and Cramer's *V* for categorical variables, will be calculated to quantify the impact of the course on the evaluated variables.

The results obtained will help identify the effectiveness of the course in improving healthcare professionals' knowledge and perceptions about living donor KT, which can serve as the basis for future training strategies and for optimizing equitable access to KT within Spain.

#### ***Phase 4. Integration of findings and contribution to the ATRAE national plan***

In the fourth and final phase of the project, the results obtained in the previous stages will be triangulated and synthesized to generate comprehensive, evidence-based knowledge (objective 6). This phase is conceived as an integrative component that will enable the transfer of research findings into actionable recommendations, directly contributing to the development of the national strategy for improving access to KT in

Spain. The synthesis will support the creation of a consensus document within the ATRAÉ project: Optimizing Access to Kidney Transplantation in Spain. ATRAÉ is a national initiative led by the ONT, the Transplant Commission of the Interterritorial Council of the Spanish National Health System (CIT-SNS), and the Spanish Society of Nephrology (SEN), in collaboration with the Spanish Association of Urology (AEU), the Spanish Society of Nephrology Nursing (SEDEN), the Spanish Society of Immunology (SEI), and the Spanish Transplant Society (SET), and with the participation of the National Federation of Associations for the Fight Against Kidney Diseases (ALCER).

The research team will analyze and interpret the findings from both the quantitative and qualitative components, applying a triangulation process to enhance the validity and depth of interpretation. The results will be structured around key thematic areas such as regional disparities, evaluation and KT access processes, healthcare professional training, and the influence of social and structural determinants. Based on this synthesis, technical briefs will be prepared to highlight the most relevant insights, propose improvement strategies, and identify aspects that require further attention. These materials will be shared with the ATRAÉ working groups and coordination bodies, with the goal of supporting evidence-based decision-making and facilitating the integration of research findings into ongoing national planning processes.

Through this knowledge translation effort, the study positions itself as a relevant and timely contributor to the development of public policies, ensuring that its findings are not only scientifically rigorous but also transferable, actionable, and aligned with the institutional framework responsible for promoting equity in access to KT in Spain.

## **ETHICS AND DISSEMINATION**

This project is grounded in the four fundamental ethical principles that guide health and social care research and practice: autonomy (respect for persons), beneficence, non-maleficence, and justice. These principles are aligned with the ethical framework set out in the Declaration of Helsinki <sup>38</sup> and the Code of Ethics for Nurses <sup>39</sup>. The study also complies with data protection regulations, including Spanish Organic Law 3/2018 of 5 December, on Personal Data Protection and Guarantee of Digital Rights <sup>40</sup>, and Regulation (EU) 2016/679 of the European Parliament and Council on data protection <sup>41</sup>.

The protocol was approved by the ethics committee of the study institution (Comitè d'Ètica de la Investigació amb Medicaments, “Ethics Committee for Research with Medicines”) under registration number 2025/12128/I. Each phase of the project will be governed by a specific research protocol, ensuring full compliance with all ethical and legal requirements. All participants will receive an information sheet and will sign an informed consent form prior to data collection. Any substantial amendments to the protocol will be submitted to the ethics committee before implementation.

The study is expected to generate significant contributions to the identification of treatment deprivation and the improvement of care pathways for people with CKD in the Spanish healthcare system. It addresses a critical gap in current knowledge by exploring the hypothesis that structural, territorial, and professional factors may contribute to inequities in access to KT. By adopting a mixed-methods approach, this protocol aims to produce empirical evidence that will test and refine this hypothesis in the Spanish context.

To ensure transparency and replicability, the methodological details will be clearly reported in all research outputs, enabling other researchers to apply or adapt the approaches used while upholding ethical standards.

The findings of the study will be disseminated through peer-reviewed publications in high-impact journals and presented at national and international conferences to promote knowledge sharing and scientific dialogue. Dissemination efforts will also include non-academic channels, such as social media, newsletters, and patient forums, to ensure accessibility and engagement among key stakeholders, including healthcare professionals, policymakers, and the general public. This multi-pronged dissemination strategy is designed to support the translation of evidence into clinical practice and health policy.

Importantly, this project aligns with national strategic planning efforts, particularly the ATRAE initiative. In its final phase, the study will triangulate and translate the generated evidence into actionable recommendations to inform the development of the ATRAE consensus document. These findings will help identify priority intervention areas, support the reinforcement of existing strategies, and uncover unmet needs, thus contributing to the formulation of timely, relevant, and policy-oriented solutions.

Operational challenges, such as the complexity of coordinating data collection across multiple healthcare centers, are anticipated. Addressing these challenges will require

rigorous planning and collaboration with local teams to ensure consistency and representativeness across diverse regions. While the variability among healthcare settings may introduce complexity, it is also seen as an opportunity to enrich the analysis by capturing the heterogeneity of the Spanish healthcare landscape.

Ultimately, the socially grounded and mixed-methods approach of this study is expected to offer a nuanced understanding of the mechanisms underlying inequity and treatment deprivation in access to KT. The insights generated may contribute to shaping public health strategies that are more equitable, efficient, and person-centered for individuals living with CKD.

**Abbreviations.** AEU, Spanish Association of Urology; ALCER, National Federation of Associations for the Fight Against Kidney Diseases; ATRA project, Optimizing Access to Kidney Transplantation in Spain; CIT-SNS, Transplant Commission of the Interterritorial Council of the Spanish National Health System; CKD, Chronic Kidney Disease; GRAMMS, Good Reporting of A Mixed Methods Study; KT, Kidney Transplantation; MeSH, Medical Subject Headings; ONT, Organización Nacional de Trasplantes; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RRT, Renal Replacement Therapy; SEDEN, Spanish Society of Nephrology Nursing; SEI, Spanish Society of Immunology; SEN, Spanish Society of Nephrology; SET, Spanish Transplant Society; SPSS, Statistical Package for the Social Sciences.

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**Authors' contributions.** GPR, CV, and BDG made substantial contributions to the conception and design of the study. MSD, LRM, MSS, and EIC critically revised the manuscript for important intellectual content and will be part of the leading group of the project. All authors read and approved the final version of the manuscript. CV, EIC, and BDG contributed equally as senior authors and are part of the project's core operational team, providing strategic, logistical, and administrative support. GPR takes responsibility for the paper as a whole and is the first and corresponding author.

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**Availability of data and materials.** The datasets generated during the proposed study protocol will be available from the first author (GPR) upon reasonable request.

**Ethics approval and consent to participate.** This protocol was approved by the ethics committee at the study institution (Comitè d'Ètica de la Investigació amb Medicaments, "Ethics Committee for Research with Medicines") with registration number 2025/12128/I.

**Competing interests.** The authors declare no competing interests.

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