

Examining Organ Donation and Transplantation Policies: Presumed or Informed Consent to Increase Donations

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Abstract

All over the world, organ donation and transplantation demand is exceeding the supply, creating huge organ shortage problems resulting in long waiting lists. While many people are waiting for donors, policymakers debate the best ways to increase organ donation and transplantation rates. Although the European Union created its 2009-2015 Action Plan, in 2022, it continues to discuss new steps to tackle the organ shortage problem. The public policy literature primarily focuses on the effect the legal consent system (either presumed or informed consent system) has on organ donation rates. While some scholars conclude that changing the legal system to presumed consent increases organ donation rates, others state that the results are ambivalent and not statistically significant. Almost all authors agree, however, that the switch of the consent system alone is not sufficient and other changes alongside (such as introducing transplantation coordinators or improving the organ donation criteria) are necessary to increase organ donation rates. The empirical part of this thesis uses regression analysis. It reveals that in the European Union countries in 2011-2019, the presumed consent system is associated with higher rates of deceased and living organ donations but with lower rates of living organ transplantations. The findings suggest that the switch of the consent system can contribute to the goal of increasing organ donation rates.

Keywords: presumed consent, informed consent, organ donation, transplantation

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Table of Contents

Abstract	i
List of Figures	iv
List of Tables	iv
Introduction	1
Theoretical framework	6
Background information on EU organ donation and transplantation policies	6
Conceptual framework	8
Literature review	10
Cases of success – Spanish and Welsh models	10
Literature analysis	14
Hypotheses	19
Factors influencing the rates of organ donation	19
Methodology and case selection	21
Case selection	21
Data sources	21
Method	25
Findings and results	27
Findings	27
Empirical results	33
Possible limitations	37
Conclusions and policy recommendations	39
Conclusions	39
Policy recommendations	41
Appendix 1: Organ Donation System in the EU	42
Reference list	43

List of Figures

Figure 1. Total number of actual deceased donors in 2011	11
Figure 2. Total number of actual deceased donors in 2019	11

List of Tables

Table 1. Descriptive statistics
Table 2. The difference between the consent systems in the EU, 2011-2019
Table 3. Regression table, informed consent and the deceased donation rates, 2011-201929
Table 4. Regression table, informed consent and the deceased donation rates, time dummies,
2011-2019
Table 5. Regression table, informed consent and living transplantations, 2011-2019
Table 6. Regression table, informed consent and the donation rates, excluding Spain, 2011-
2019
Table 7. Regression table, informed consent and living transplantations, excluding Spain, 2011-
2019

Introduction

Despite the technological advancements and brand-new technologies in the field of medicine, organ donation and transplantation remain one of the primary ways to prolong a person's life or improve its quality in case of various medical conditions. The question of how to enhance organ donation policies is debated all over the world. The European Union (EU) enacted the 2009-2015 Action plan on Organ Donation and Transplantation, intending to strengthen the cooperation between the EU Member States (European Commission 2008). In addition, the European Commission (hereafter – EC) established a Thematic Network, a set of regulations that aimed to create the key action points for Member State countries to increase organ donation and transplantation levels within the continent (Vanholder et al. 2021). However, the organ demand still significantly exceeds the supply in all Member States, and the rates still differ considerably among them; thus, additional steps are necessary to minimize the existing waiting lists and tackle the donor shortage problem (Scholz 2020).

There are plenty of reasons why organ donation stands out as one of the most critical health policy issues in the EU on both individual and societal levels. Looking at organ transplantation from a socio-economic perspective, transplantation serves as a means to an end to improving patients' quality of life, consequently minimizing the socio-economic burden on societies that would otherwise bear the costs of treatment for those in need (Vanholder et al. 2021). Furthermore, the diseases of people who need transplantation create a burden on national healthcare systems and economies (e.g., rising unemployment). In 2021, 77% of the disease burden and 86% of deaths were caused by non-communicable diseases (NCDs); more often than not, transplantation is the sole treatment for such conditions (Vanholder et al. 2021). When illustrating the costs that healthcare systems encounter, Vanholder et al. (2021) indicated the economic evaluations revealing that liver transplantation is cost-effective compared to non-transplanted liver disease due to medications, procedures, and prolonged hospital admissions.

Since livers are second to kidneys among the most frequently transplanted organs in the EU (Scholz 2020), the increased numbers of donations can not only help citizens to prolong their lives but also save money from the state budget.

Even though the importance of the topic is evident, policymakers need to take into account various medical, religious, cultural, and ethical considerations when enacting changes in this field (European Parliament 2020; Lewis et al. 2021). Alongside these debates, there are many ways to increase the rates of transplantations, such as changes in the coordination process, engagement of certain communities, benchmarking (adjusting the commonly adopted organ donation standards), and expanded donor criteria (Vanholder et al. 2021). Meanwhile, the academic literature debate on this topic is mainly concerned with the organ donation consent system in the first place. Essentially, there are two most common systems - presumed consent (opt-out) and informed consent (opt-in). The main difference between the two is that the "presumed consent" system considers a person consenting to the organ donation unless they specifically ask to be removed from the list (Vanholder et al. 2021). The informed consent system means the opposite - the person is not in the organ donation registration system unless they ask to be in it (Vanholder et al. 2021). Most authors agree that the sole change in the system is not sufficient enough for the drastic improvements in organ donations (Rudge 2018; Arshad, Anderson, and Sharif 2019; Coppen et al. 2005; Etheredge 2021). However, in spite of their suggestive conclusions, the authors still fail to provide a precise answer to whether a change in the system has a statistically significant impact.

Despite the lack of proof and data on finding the best ways to increase organ donation and transplantation rates, countries around the world, including the EU ones, are still considering and changing their systems from informed to presumed consent with the hope of increasing the rates. Recent examples include Greece (2013), the Netherlands (2020), and the United Kingdom (2020) (Symvoulakis et al. 2013; Jansen et al. 2022). One of the main reasons why scholars are supporting the consent system change is the internal beliefs towards organ donations. In other words, the policy of presumed consent could potentially change the societal attitude in favor of donations (English et al. 2019; Etheredge 2021; European Parliament 2020; Lewis et al. 2021; Vanholder et al. 2021). In addition to that, a transition is a solution that governments can follow to achieve better donation rates without substantial financial costs. However, even after the change of the system, in some cases, the donation rates remain low, and there is a heated debate within the academic community if the presumed consent system is statistically significant in increasing the donation rates.

The thesis addresses some of the gaps in the literature and attempts to explain the contradictory findings on the association between the consent system and organ donation and transplantation rates. The gaps identified in the literature are: 1) The quantitative research mainly includes indicators of wealth and education, including a maximum of one factor measuring the quality of the healthcare system. Qualitative research, on the other hand, states that such factors as the number of ICU beds, number of nurses, or healthcare expenditures make significant differences in organ donation rates. Therefore, this paper includes more indicators that measure the quality of the healthcare system. 2) In addition to that, the existing research uses data from the same period that is also old (1996-2004). The most recent quantitative study by Arshad et al. (2016) stated that including more recent data could impact the findings. These scholars also stated that using the data from the same periods could lead to homogeneity of the results. Thus, by using 2011-2019 data, this thesis tests the findings of the Arshad et al. (2016) paper to see if other studies found correlations between the presumed consent system and higher rates of organ donations due to homogeneous data. 3) Finally, the thesis analyses only the EU countries, which is a homogenous region with unified laws on the safety and quality control of organ donation and transplantation. This research benefits the EU policymakers with its targeted policy recommendations.

This paper aims to extend the previous studies and address the limitations concerning the effect of the presumed versus informed consent system. The **research question is what effect does the informed consent organ donor system have on the rates of organ donation among the European Union countries in 2011-2019?** In addition to that, by analyzing the cases of Spain and Wales, considered to be leaders regarding organ donation rates, this paper also offers recommendations for all EU countries on how to improve the donation rates.

The consent system is one of the primary indicators considered in the academic literature that could be analyzed quantitatively. Thus, in this research, the consent system is the independent variable measuring the effect of the existing system on the rates of organ donation. The dependent variables are the total number of deceased organ donations and living kidney and liver transplantations. In addition to that, to avoid the omitted variable bias¹, additional observed control variables are selected based on the analyzed literature: Gross Domestic Product (GDP) per capita, Intensive Care Unit (ICU) beds per 1000 people, hospital beds per 1000 people, nurses per 1000 people, religious affiliation, and the healthcare expenditures as a % of GDP. The panel ordinary least square regression with the time dummies is used to see the associations between the legal donor consent system and the organ donation and transplantation rates.

Results of the empirical analyses discovered that: 1) informed consent system is associated with lower deceased organ donation rates with the results being statistically significant; 2) informed consent system is associated with higher living kidney transplantation rates; 3) included covariates have statistically significant results, but the coefficients proved to be too small to make robust estimates; 4) in countries where Christianity is the predominant religion, the deceased organ donation rates were lower.

¹ Omitted variable bias emerges when the variable that is omitted actually causes the independent and dependent variable.

The structure of the thesis is the following: first, the theoretical framework briefly defines the background of the EU policies towards organ donation and transplantation, presents the conceptual framework, and introduces the debate on the topic in the literature. It also provides the hypotheses of this work. Second, the methodology chapter discusses the method, sources of the collected data, and case selection. The third chapter introduces the empirical strategy and presents detailed empirical results, together with the possible limitations. The fourth chapter discusses the conclusions of the research and provides policy recommendations on how to better increase the rates of organ donations.

Theoretical framework

The theoretical framework is divided into four parts: first, the background information section presents the EU healthcare policies, specifically those concerning organ donation and transplantation. Second, the conceptual framework introduces the definitions of organ donation, the division of deceased and living donors, as well the existing legal consent systems: presumed and informed consent. Second, the literature analysis presents the academic debates on the effect of the change in the legal consent system and the main factors contributing to the higher donation rates. Additionally, the cases of Spain and Wales are described to see the good practices other countries should follow. Finally, the hypotheses for this paper are introduced based on the literature review.

Background information on EU organ donation and transplantation policies

Currently, among the 27 EU countries, 6 countries still have the informed consent system (see the complete list in Appendix 1: Organ Donation System in the EU). While more countries have already changed their systems to that of presumed consent, it is essential to note that the organ donation rates are still insufficient, and any additional instrument to increase the rates is welcomed in the EU. The European Commission admits that the presumed consent system contributes to higher donation rates (Scholz 2020). However, the decision on which consent system to implement is still under the discretionary freedom of MS, and the EU Directive is neutral on this question (den Exter 2017).

According to the EU, the issue of low numbers of organ donation and transplantation is perceived as "one of the initial health priorities of the current Croatian Presidency of the Council of the EU" (Scholz 2020, 1). In the Programme of the Croatian Presidency of the Council of the EU, the Presidency stated that they would make "special efforts to explore the possibilities of closer and improved cooperation among Member States" (Croatian Presidency of the Council of the European Union 2020, 29). To put the figures into perspective, in 2020, there were 35 529 transplanted organs and 43 183 new patients added to the waiting list in Europe (Dominguez-Gil 2021). While the responsibility towards organ donation is concerned chiefly at the country level, the EU can mainly adopt the quality and safety standards in all stages of the process – from organ donation and procurement to transplantation (Article 168) (Scholz 2020). When MS implement the measures, EC invites countries to share their best practices in the regularly held meetings. Cooperation is seen to be the key element in easing the way of transplantation around the countries. Currently, the EU countries do not have a unified transplantation scheme. There is a Eurotransplant organization that allocates the donor organs in eight MS: Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, Netherlands, and Slovenia (Eurotransplant 2022). In addition to that, there is the Scanditranspalnt which unites 3 EU MS: Estonia, Sweden, and Denmark. The network also included three non-EU territories: Greenland, Iceland, and Norway (Scanditransplant 2022). The respective organizations are the mediators between the donor and recipient when distributing the donor organs for transplantation. Despite the fact that organizations portray themselves as successful and reaching their goals (Smits et al. 2002), these networks do not unite all the EU MS, therefore, the cooperation between the EU countries should still be considered.

In the EC 2009-2015 Action Plan, it was mentioned that Article 152(4) (a) of the EU Treaty concerns public health and allows the European Commission to adopt harmonizing measures and ensure organ quality and safety (European Commission 2002). Following this Article, three objectives were raised: a) increase organ availability; b) enhance the efficiency and accessibility of transplantation systems; c) improve quality and safety (European Commission 2008). Every country was told to create its own Sets of National Priority Actions based on the suggested priorities in the joint EC Action Plan. In 2012, the European Parliament again stressed the importance of organ donations and asked every country to conduct awareness-raising campaigns together with ensuring clear and available medically-based

information for the general public (European Parliament 2012). In addition to that, the government of Spain was asked to lead on EU policy on organ donation and transplantation as it has always proved to be the leader in this field (Rada 2011). When a quantitative impact evaluation of the Action Plan was not conducted, the qualitative study on the update and impact of the EU plan (Bouwman et al. 2017) revealed that the Plan helped countries to create their national plans and improve existing policies. In 2020, Hilde Vautmans, the leading Member of the European Parliament in the field of organ donation, stated that EC should reshape the current legislative framework (Fortuna 2020). So far, the new Action Plan has been postponed due to COVID-19, and the European Union only held a public communication campaign on the European Day for Organ Donation and Transplantation on the 9th of October in 2021, with a slogan "JustSayYes" (Council of Europe 2021). Even though a further note on the transplantation and cooperation on organ donation among the EU countries was not released, the long waiting list for patients and low organ donation rates are worsening the EU citizens' everyday life.

Conceptual framework

Delving into the concept of organ donation more thoroughly, this paper uses the definition stated by the EU, which is "the act of giving one or more organs (or parts thereof), without compensation, for transplantation into someone else" (European Parliament 2020). The definition includes both deceased donations and living transplantations. Deceased donation means that organs come from donors who suffered from a brain or circulatory death (European Parliament 2020). This is the most prevalent transplantation form in the EU (Vanholder et al. 2021). Living transplantations, on the other hand, describe the acts of donating the organ (or part of the organ) for transplantation to another person (including but not limited to the family members) when the donor is still alive and conscious (National Kidney Foundation 2015).

As for the legal consent systems that prevail around the world, there are two organ donation systems – those of presumed and informed consent. Presumed consent, or opt-out system, implies that consent is presumed unless the donors officially register their refusal to donate their organs. Currently, it is approximated that countries with presumed consent have higher donor rates (depending on the studies, from 23.3% to 61.5% increase rate) (Vanholder et al. 2021). In other words, it allows for the 're-branding' of donations as a standard procedure (Lewis et al. 2021). The presumed consent system also requires less physical, emotional, and administrative effort when making a choice of whether to donate the organs (Lewis et al. 2021). It is important to note that there could be soft and hard presumed consent systems. Hard presumed means that families are not asked about their relative's organ donation after death (e.g., Singapore, Austria), and in the case of the soft presumed family makes the final decision and is under any circumstance consulted by nurses and coordinators (in most of the countries) (Noyes et al. 2019). Informed consent, or the opt-in system, on the other hand, means that the consent for donation is specifically sought from donors and their families (Vanholder et al. 2021). As in the case of the soft presumed consent systems, in informed consent countries, even when you have the donor card and make informed consent before your death, your family is still consulted after your death (e.g., Lithuania) (Costa-Font, Rudisill, and Salcher-Konrad 2021).

Based on a recent study analyzing the emotional barriers and attitudes toward organ donations, in the cases of both systems, family refusal is considered a central factor in low organ donation rates (Miller et al., 2020). However, it is important to note that the type of presumed consent organ donation system in a country itself does not have significant effects on the decisions of families on whether to donate, which in turn does not have any significant effects on donation rates (Abadie and Gay 2006; Sharif 2018). What makes the key difference when families have to make a decision of whether to donate is whether a healthcare staff talks

to the family about the procedure. In other words, according to the available studies and data, consultations with families need to be sensitive and professional as it is one of the most critical steps of the organ donation process (Noyes et al. 2019). Therefore, the following literature analysis and empirical study will not differentiate hard and soft presumed consent systems separately.

Literature review

Below, before the literature analysis, cases of Spain and Wales will be shortly introduced to see what the academic community considers to be the exemplary case of how organ donation could be increased in a country.

Cases of success – Spanish and Welsh models

Spain is considered to be a worldwide success case in terms of organ donation systems. Many authors have been trying to understand the conditions for the country's success (Shepherd, O'Carroll, and Ferguson 2014; Sharif 2018; Etheredge 2021; Sharif 2017; Matesanz, Domínguez-Gil, et al. 2017; Matesanz, Marazuela, et al. 2017). Figure 1 and Figure 2 depict the total number of deceased organ donations (per million population, p.m.p.) in the EU in 2011 and 2019. It is clear that Spain is the leader in the number of organ donations through the selected period.

Figure 1. Total number of actual deceased donors in 2011



Source: compiled by the author based on the (GODT 2021). Countries in white color had an informed consent system in 2011.



Figure 2. Total number of actual deceased donors in 2019

Source: compiled by the author based on the (GODT 2021). Countries in white color have an informed consent system in 2019.

In 1979 the Spanish government passed the law changing the organ donation consent system from the informed to the presumed organ donor register consent system (Quigley et al. 2008). Later on, the government continued to make improvements to organ donation policies. Based on the government's calculations, the organ shortage caused high expenditures on the budget since dialysis as a replacement therapy surpasses the cost of the transplantation procedure (Matesanz, Marazuela, et al. 2017). In 1989, a holistic transplantation system was introduced, with the new addition of a transplant coordination network which to this day continues to operate at every hospital at regional and national levels (Shepherd, O'Carroll, and Ferguson 2014; Healthcare in Europe 2012). Moreover, sustained investments into nurses' and transplant coordinators' training also allowed for maximizing the organ donation possibilities (Sharif 2017). In addition to the changes in the healthcare sector, investments into education played a pivotal role. The government developed educational programs "to offer the transplant coordinators the best strategies for transmitting messages to media professionals" (Miranda et al. 1999, 16). Alongside these changes, a communication campaign with the general public was introduced. Together with the public communication campaign, the government made a clear effort to try and change the general attitudes of the public toward organ donations (Sharif 2018). In other words, the Spanish government precisely integrated the organ donation system into the whole state healthcare system, combining training, communication, and coordination.

Specifically, in order to raise donation numbers, in 2008, the Spanish government introduced "The 40 Donors per million population Plan" and made crucial changes in the following two ways (Matesanz, Domínguez-Gil, et al. 2017):

- The government created an early referral list of potential donors by identifying the donors outside the ICU and incorporating the organ donation option into end-of-life care. Also, the National Transplantation Organization was established in 2009. It identified the hospitals that would best suit different phases of donation. In addition, the coordinating doctors were trained (Matesanz, Marazuela, et al. 2017).
- 2) The criteria of possible donors were expanded. Firstly, age limitations were changed. Scholars provided the data that in 2015, more than half of the deceased donors were over 60 years old and 10% of the donors were older than 80 years old (Matesanz, Domínguez-Gil, et al. 2017). Therefore, the "old-for-old" program was

established, where the aged elderly donors dying of cerebrovascular accidents were considered to be donor candidates (Matesanz, Domínguez-Gil, et al. 2017). Additionally, non-standard risk donors were also given a second opinion on whether they could become donors. For this reason, a 24/7 available medical team was introduced, allowing donor coordinators to get a second opinion on the medical suitability of potential donors. In conclusion, the donor selection criteria became more flexible.

When looking at the good practices, another recent donor consent system switch, together with the structural healthcare system changes, was implemented in Wales (Noyes et al. 2019). Wales changed the consent system in 2015 (Welsh Government 2019). Even though the system switch in Wales from informed to presumed consent is relatively recent and there is not enough data to make an impact analysis, nonetheless, one qualitative study showed positive results on donation rates. Noyes et al. (2019) conducted interviews with family members and professionals and concluded the change of the system was a "success." However, they pointed out that the system change was not the single variable and ongoing training and support for nurses were even more important. Alongside the changes to the organ donation model, in all territories of the United Kingdom, a new healthcare practitioner role was introduced called the Specialist Nurses in Organ Donation (SNODs). These nurses are specifically trained by the authorities responsible for organ donation and transplantation (Noyes et al. 2019). Evidence revealed that SNOD intervention with families during vulnerable situations is an excellent way to increase the consent rate of the relatives after brain death (Noyes et al. 2019). In addition to that, Wales also introduced a communication campaign for the general public and retrained the specialist nurses and other staff.

The Spanish Model and recent success in Wales prove that various factors could influence organ donation rates. It is important to present these individual cases in more detail in order to introduce the qualitative factors that influence organ donation rates. As most of the research on the topic analyses large quantitative datasets, presenting the findings of qualitative studies which use the sources of primary actors involved in the donation process (be it nurses, various organizations, or relatives) allows to more concretely identify the information gaps. It also indicates more variables that could be used in quantitative analysis.

Literature analysis

Organ donation and transplantation topics have been discussed in academic literature since 1980. Yet, the agreement on whether the system makes a difference in organ donation rates was not met. Even though most authors agree that the system itself could, to some extent, have an impact on donation rates, additional factors, such as the number of healthcare staff, ICU beds, or (non-)existent efforts to make targeted marketing campaigns, are also crucial.

On the one hand, several studies found a statistically significant effect of the presumed consent system on organ donation rates (Abadie and Gay 2006; Shepherd, O'Carroll, and Ferguson 2014; Rithalia et al. 2009; Horvat et al. 2010). Abadie and Gay (2006) analyzed 22 countries during a 10 year period (1992-2002) to see if and how deceased organ donors' legislation is related to organ donation rates. Their analysis included but was not limited to European Union countries. Scholars used regression analysis to see the effect of the legislation on organ donation and transplantation rates. In addition to that, they calculated the donor's contemplation costs. It was found that citizens living in informed consent countries are unwilling to register themselves as donors since contemplation costs exceed their perceived value. Arshad et al. (2019) agree with the contemplation costs analysis, and in their study, they state that in the case of presumed consent, the gap between the intention and act is minimized. Abadie and Gay (2006) also proposed other factors that could help to alleviate the existing organ shortage problem, such as financial incentives for the donors, educational campaigns, and organ exchange mechanisms for living donors with incompatible recipients. Their

regression analysis controls various determinants, including GDP pc, heath expenditures pc, religious beliefs, the system itself, the number of deaths caused by motor vehicle accidents, and cerebrovascular diseases (Abadie and Gay 2006). The results revealed that the presumed consent countries have 25-30% higher donation rates for deceased donors than those with the informed consent system.

Another similar panel study was conducted by Shepherd et al. (2014). The authors examined three factors, including the 1) number of both deceased and living donations, 2) transplantation rates for different types of organs, and 3) the causal factor between organ donation rates and the presumed consent system (Shepherd, O'Carroll, and Ferguson 2014). They included 48 countries over the 13 years (2000-2012) and used the time-invariant covariates, such as legal system, GDP pc, number of hospital beds, and percentage of Catholics. They also used the mean of the GDP over the 13 years to see whether the country's wealth over time makes a difference in the donation rates. Authors found out that the number of deceased donors and the total number (deceased plus living donors) is higher in the presumed consent system. However, the rates of living donors are higher in the countries with an informed consent system (Horvat et al. 2010; Sharif 2018; Shepherd, O'Carroll, and Ferguson 2014). Needless to say that the rates of living transplantations are slightly less important than the deceased organ donations as only a few organs can be transplanted from the living donors (Sharif 2018). Even if there is a positive causal relationship between the opt-out system and the donation rates, Shepherd et al. (2014) concluded that all countries are still facing problems of significant transplant waiting lists and are not addressing the shortage of organ donors. Thus, the system itself could hardly solve the issue entirely, and other factors must be considered alongside organ transplantation systems' transformation.

On the other hand, other authors state that no statistically significant results prove that there is a positive association between the presumed consent system and organ donation rates (Rudge 2018; Coppen et al. 2005; Rithalia et al. 2009; Sharif 2018; Etheredge 2021). Rudge (2018) provides the example of Spain as a success model and says that other factors must be taken into account if the country seeks to improve the donation rates. He mentions that the medical personnel and ICU beds play an essential role in the complete transformations of the existing transplantation systems (Rudge 2018). Sharif (2018) also pointed out that the infrastructural changes, including the number of ICU beds, are crucial and added that without public communication campaigns, donor rates would not change. He said that the changes in the system in different countries could have contrasting effects. For instance, Belgium is seen as a success case, while the data shows ambivalent results in the Swedish case (Sharif 2018).

Similar conclusions were drawn from the most recent quantitative study comparing the organ donation rates between the two systems (Arshad, Anderson, and Sharif 2019). Scholars conducted a cross-sectional analysis of 35 Organisation for Economic Co-operation and Development (OECD) countries from 2012-2016. After conducting the regression analysis, they concluded that presumed consent countries have fewer living donors and a slightly higher number of deceased donors (statistically insignificant results). However, the difference in organ donation rates between the two systems was statistically insignificant (Arshad, Anderson, and Sharif 2019). Again, other factors, such as whether the general public was educated about the importance and benefits of transplantation, were introduced. The same conclusions were made by Coppen et al. (2005), who used the 2000-2002 data and found no statistically significant difference in donor rates between the two systems.

Other authors analyze the organ donation rates from a slightly different angle and mainly focus on the psychological factors. They discuss that in the countries where presumed consent is adopted, citizens understand it as a 'default' or 'right' option, meaning that they are not only more willing to donate their organs but also more willing to agree with their relative's organ donation when it is necessary (Sharif 2018; Davidai, Gilovich, and Ross 2012; Shepherd, O'Carroll, and Ferguson 2014). This happens because people are generally lazy and prone to procrastination when it comes to decision-making (Davidai, Gilovich, and Ross 2012). Furthermore, regardless of the type of organ donation system a country follows, more often than not, on a personal level, people tend to stick to the default option that the system implies without additional questions and concerns, either be it a default-donor or a default-non-donor people tend to stick attach their norms and beliefs to both systems, and when the consent system is presumed, it looks like the one that a person more often than not simply follows without additional questions and concerns (Davidai, Gilovich, and Ross 2012).

To conclude, most of the authors agree that the system alone does not make a substantial impact on organ donation and transplantation rates since other policy changes have to follow as well (Coppen et al. 2005; Noyes et al. 2019; Sharif 2017; Matesanz, Domínguez-Gil, et al. 2017; Etheredge 2021). However, debates over changes to the organ donation consent system from informed to presumed consent are still taking place in some EU countries. For instance, the Lithuanian government is considered making a switch, yet it states that there is a lack of evidence of whether a presumed consent system guarantees higher organ donation rates (Andrukaityte 2022).

This thesis fills the certain gaps that existing literature has not addressed yet:

1) Most importantly, the presented literature does not include covariates of wealth and quality of the healthcare system in the same regression analysis. While some of the authors are more concerned with the wealth aspect of the selected countries (Arshad, Anderson, and Sharif 2019), others mainly focus on education and quality of the healthcare system covariates (Shepherd, O'Carroll, and Ferguson 2014). However, as was demonstrated by both qualitative and quantitative studies and the analysis of the Spanish Model, all these covariates could be equally important in the equations when understanding the associations between the consent system and

the donation rates. The covariates that measure the quality of the healthcare system allow to better understand the strength of the correlation that the system alone could make. In this thesis, the four covariates that indicate the quality of the healthcare system are: healthcare expenditures, number of ICU beds, number of hospital beds, and number of nurses.

- 2) Even though many studies have already analyzed the effect of the consent system, however, none of the analyses considered EU countries separately. The analysis of EU countries separately from others is essential because the EU has its unified policy and plans the new Action Plan for organ donation and transplantation. Thus, this thesis will fill the gap for EU policymakers to see whether the change of the system plays a role, as well as for the scientists to give more clarity to the current discussion. The 6 EU countries that still have the informed consent system might be encouraged to change their policies if the results prove to be statistically significant. Moreover, if all EU countries had the same type of legal consent system, it would be easier to create an EU-wide donor registry system.
- 3) Finally, the most recent quantitative analysis by Arshad et al. (2016) stated that the period of the used datasets could be the crucial factor affecting the study results. Previous analyses used data from the same period, which was also old. Thus, by analyzing the newest data available up to the year of 2019, this thesis allows to test Arshad et al. (2016) study conclusions that positive correlations between presumed consent system and higher rates of organ donations appeared due to homogeneous data.

Hypotheses

Before moving to the methodology and case selection, it is essential to raise the hypotheses related to the aforementioned research question concerning the effect of the organ registering system on the rates of organ donation.

Factors influencing the rates of organ donation

Based on the literature review, organ donation rates could be highly influenced by the wealth of the country as measured by the GDP pc, number of nurses, number of hospital beds, number of ICU beds, healthcare expenditures, and dominating religious affiliation.

In terms of wealth and healthcare expenditures, it is believed that the wealth and development of the country could positively impact the rate of organ donation and transplantation (more investments in the healthcare system, better developed administrative policies, as well as more effective coordination) (Rudge 2018; Arshad, Anderson, and Sharif 2019; Abadie and Gay 2006; Shepherd, O'Carroll, and Ferguson 2014). In relation to that, countries with higher expenditures on the healthcare system are also expected to have increased organ donation rates (Arshad, Anderson, and Sharif 2019; Abadie and Gay 2006). Furthermore, countries with more staff working in the healthcare sector and better infrastructure (more ICU/hospital beds) are expected to have higher organ donation numbers.

Lastly, several studies showed that religious affiliation could correlate with organ donation rates (Lauri 2010; Randhawa et al. 2010). However, the opinions in the academic community differ. Randhava et al. (2010) studied the views of the United Kingdom's faith leaders and found that they opposed the system changes from informed to presumed consent. Contrastingly, more scholars are stating that Christianity and its values promote organ donation. Lauri (2010) did a qualitative analysis of Maltese people and their attitudes towards donations. Results revealed that the Catholic Church was the main factor influencing citizens' opinions. As giving organs is related to altruism, people perceive it as a good action (Lauri 2010; Oliver, Ahmed, and Woywodt 2012). Even more, the Church of England declared organ donation a Christian duty (Lauri 2010). Bresnahan and Mahler (2010) analyzed attitudes of the five main religions towards organ donation. They concluded that Catholicism sees donations as "an act of charity and love" (Bresnahan and Mahler 2010, 59).

The hypotheses of this thesis are the following:

H1: Informed consent system is associated with lower organ donation rates than the presumed consent system.

H2: Informed consent system is associated with higher living organ transplantation rates than the presumed consent system.

Methodology and case selection

This chapter briefly presents the reasons for the selected case and describes the used method and sources of independent, dependent, and instrumental variables used in the regression analysis.

Case selection

To answer the research question, what effect does the informed consent organ donor system do on the rates of organ donation among the European Union countries in 2011-2019, the European Union countries were selected due to three main reasons: a) the unified organ donation and transplantation policies concerning the standards of quality and safety; b) the relatively high development; c) data availability.

A unified organ donation and transplantation standard means that the EU has a common organ donation and transplantation policy set in the EU Treaty. That allows selected countries' policymakers to have easily comparable cases as the same rules bind all countries. In addition to that, there are regularly held meetings on transplantation topics to share good practices among the EU countries.

The second reason, mentioning the development, the EU was chosen due to a more even comparison in the quantitative analysis since it is a relatively homogenous region.

Third, data availability was also an important reason. Even though there was no unified dataset for all selected variables, most of the data was provided in Eurostat or other similar databases for all European Union countries.

Data sources

The research initially included 27 European Union countries during a 10 year period (2011-2020). All countries published their data on organ donation and transplantation rates in the Global Observatory on Donation and Transplantation (GODT). Then, after collecting these statistics, specific criteria were used to select which EU countries would be included in the

final study. Based on the data comparability, three countries with a population below one million (Malta, Luxembourg, and Cyprus) in the given period were not included in the study because the data for the deceased and living organ donation is provided per million people, and their estimates could bias the final results.

As for the selected research period, although 2011-2020 data on donation and transplantation rates was provided for all EU countries on the GODT database, 2020 data on selected control variables was missing in most cases. Thus, the analysis was shortened to 2011-2019 and included 243 observations (Table 1).

In this research, there are three main outcome variables, all of which are taken from the GODT database (GODT 2021): 1) actual deceased organ donor per million population, which, according to GODT, is "a deceased person from whom at least one organ was recovered for the purpose of transplantation" (Dominguez-Gil 2021). 2) Kidney transplantation from living donors per million population and 3) liver transplantation from living persons per million population when "a living donor is a living human being from whom organs have been recovered for the purpose of transplantation" (Dominguez-Gil 2021).

The independent variable is the consent system existing in the countries. The data was taken using the Scholz (2020) paper and double-checked in other research papers, countries' transplantation websites, or national laws. There were some inconsistencies in Scholz's (2020) study regarding the legal consent system of Cyprus and Malta. However, as already mentioned, both countries were excluded from the final research due to population size.

The other seven control variables were taken from various sources as there was no unified dataset for the selected factors. These control variables are:

GDP pc. The data for the GDP per capita (current US\$) was taken from the World Bank dataset (The World Bank 2022).

22

ICU beds rate. Intensive care unit (ICU) beds per 1000 people were selected as a variable as most donors are placed in the ICU as a result of brain or circulatory death. Data for this variable was collected using the Trading Economics dataset (Trading Economics 2020a) by searching for data in each country's profile separately. The Trading Economics dataset did not include information on Bulgaria and Romania. For Romania, the Statista dataset was used, calculating the data for the 1000 citizens manually (Statista 2019c). Data for Bulgaria was collected from its national statistics portal (National Statistical Institute 2018). However, that data was provided only until 2018. In addition to that, the data for ICU beds in Croatia is missing for the entire period.

Hospital beds rate. Data for hospital beds per 1000 people were collected using The Global Economy dataset published for the OECD countries (data provided until 2018) (The Global Economy 2018). Other countries' data was taken from different websites: Bulgarian and Romanian data were collected from Statista (Statista 2019a; 2020), and Croatia's data was taken from the World Bank, however, it was only provided until 2017 (The World Bank 2017a).

Nurses rate. The Global Economy dataset was used to collect the data for the number of nurses per 1000 people (The Global Economy 2019), filling the data gaps for Bulgaria, Croatia, Finland, France, Ireland, Poland, and Portugal separately (National Statistical Institute 2018; The World Bank 2017b; Trading Economics 2020; Statista 2019b; Statistics Portugal 2021). It is important to note that the data from the World Bank dataset that was used for Croatia and Finland includes not only nurses but midwives as well. Moreover, the number of nurses in the Netherlands and Poland is provided only from 2015 onward. As for Romania, this data is provided only for the year 2018. There is also a lack of 2019 Swedish data.

Religious affiliation. The religious affiliation variable only focused on the dominant religion (or the lack of religion, thereof) in a given country. In all cases where the largest share of a country's citizens identified as being religious, the dominant religion was Christianity (of

all its different branches). There were a few cases where the largest share of a country's citizens identified as being irreligious. Therefore, the religious affiliation variable was coded as a dummy variable (1 - Christian, 0 - irreligious). The data for the variable was taken from the 2020 European Social Survey (ESS 2021).

Healthcare expenditures. The Eurostat database was used for the healthcare expenditures as a percentage of GDP variable (Eurostat 2022). Data for 2011-2013 was missing for Slovenia, and the data for Latvia was not provided for the entire period.

The descriptive statistics of the used numeric variables are presented in Table 1 below. In total, the dataset has 243 observations. In addition to that, there are two categorical variables – religious affiliation and consent system (243 observations for each).

Variable	Observations	Mean	Median	St. dev.	Min	Max
Total number of deceased donors	243	336.8	124.0	525.5	2.0	2302
Total number of deceased donors per million population	243	18.6	17.6	9.7	0.3	49.60
Number of transplanted living kidneys per million population	238	6.5	4.7	6.5	0.0	33.20
Number of transplanted living kidneys	240	624.9	242.0	899.8	0.0	3782
Number of transplanted living livers per million population	228	0.3	0.0	0.7	0.0	3.80
Number of transplanted living livers	239	248.5	75.0	386.2	0.0	1374
GDP per capita	243	33632	25683	22859.2	7075	123679
Number of ICU beds per 1000 population	221	3.8	3.6	1.4	0.2	6.41
Number of hospital beds per 1000 population	237	5.2	5.2	2.0	1.0	12.98
Number of nurses per 1000 population	221	7.9	7.4	2.9	2.5	14.90
Healthcare expenditures as a % of GDP	222	8.4	8.5	1.9	4.7	11.70

Table 1. Descriptive statistics

Source: compiled by the author

Method

The panel data pooled OLS regression was chosen to test the relationship between the consent system (independent variable) and the organ donation rates (dependent variable). Ordinary Least Squares regression helps to find the estimated equation. OLS "minimizes the sum of squared deviations between the observed values of the dependent variable and the estimated values of the independent variable" (Anderson, Sweeney, and Williams 2010, 489). The OLS assumptions must be held true when estimating the linear regression (Gaus-Markov theorem) (Theil 1971). One of the main assumptions is that the residuals come from a population that has homoscedasticity, which refers to equal variance (Gujarati 2003). In other words, each observation should have the same variance. If this is not ensured, heteroscedasticity appears, and the variance of the coefficient estimates is increased. To avoid that, the dependent variable in this paper is counted per million population to reduce the variability of the population. The fixed-effect model was not selected, as the independent variable is the informed consent system, meaning it is a dummy variable which is not suitable for the fixed-effects analysis. To answer the research question of this paper, the across country analysis is used, as we are looking for an effect between the informed consent system and the number of total donors instead of looking for an effect of the change in the system. We cannot look for the effect of the change, as during the selected period, 2011-2019, only one country (Greece) has changed the system.

The standard set of control variables is used to control the variation in the dependent variable.

The two equations – one for deceased organ donation and one for living organ transplantation - are as follows:

 $Total_donors_t = \alpha_{ti} + \beta_1 informed_{ti} + \beta_2 GDPpc_{ti} + \beta_3 ICU_beds_{ti} + \beta_4 hospital_bed_{ti} + \beta_5 nurses_{ti} + \beta_6 religion_{ti} + \beta_7 health_expenditures_{ti} + \mu_{ti}$

$$\begin{split} Living_donors_t &= \alpha_t + \beta_1 informed_{ti} + \beta_2 GDPpc_{ti} + \beta_3 ICU_beds_{ti} + \beta_4 hospital_bed_{ti} + \beta_5 nurses_{ti} \\ &+ \beta_6 religion_{ti} + \beta_7 health_expenditures_{ti} + \mu_{ti} \end{split}$$

where α_i = intercept for each country; β = coefficients; μ = error term; t = years; i = countries

It is important to note that provided linear regression is not proving any causal relations between the chosen variables. However, even without the causal link, the provided models demonstrate the correlations and show the different associations with the organ donation rate.

All regression tables below will include the R-squared and adjusted R-squared measures. R-squared allows predicting future outcomes and provides the measure of how well-observed outcomes are illustrated by the model (Fernando 2021). It is the "percentage of the dependent variable variation that a linear model explains" (Frost 2017). When we include only R-squared measurement to see how much of the model is explained, the issue arises, as R-squared increases automatically with every additional covariate (for example, if we include 100 covariates, R-squared will be high; however, that does not mean that the model will be well explained). Thus, the adjusted R-squared is also provided below. Adjusted R-squared is always less or equal to the R-squared (Potters and Eichler 2022). Also, it increases only when the increase of the R-squared is more than one would expect to see by chance (Potters and Eichler 2022), and it is a less biased estimator.

In addition to that, the two significance levels were selected: 95% significance level when the p-value is less than 0.05 (***) and 90% significance level with the p-value being lower than 0.1 (**).

Findings and results

This chapter presents the pooled OLS regression findings and discusses the regressions' results. Moreover, it indicates this thesis's limitations and gaps for future researchers. The recommendations for policymakers are provided in the section on Policy recommendations.

Findings

The regression analysis on the total deceased organ rates and all selected covariates was done to analyze the difference between the informed and presumed consent systems. The results are provided in Table 2 (statistically significant variables are highlighted in grey color). Even though the coefficients of covariates of ICU beds, hospital beds, and nurses proved to be statistically significant, the coefficients are too low to make robust estimates. In the presumed consent system, countries with the prevailing religion being Christianity are associated with lower organ donation rates (more about it in the section on Empirical results). Moreover, the presumed consent countries reveal the association between the higher level of healthcare expenditures as a % of GDP with the higher rates of organ donations.

	Informed	consent	Presume	ed consent	
	Coeff. p-value		Coeff.	p-value	
GDP_pc	0	0.395	0	0.167	
ICU beds	2.18	0.000	-2.34	0.001	
Hospital beds	-1.54	0.000	-0.28	0.433	
Nurses	-1.12	0.025	-0.58	0.081	
Christian	-2.03	0.180	-6.5	0.004	
Healthcare					
expenditures	0.45	0.294	4.24	0.000	
Intercept	20.39	0.000	10.48	0.050	
Signi	ficance levels:	·***' 0.05, ·* [;]	*' 0.01		
R-squared		0.72		0.41	
Adi R-squared	0.69 0.38				

Table 2. The difference between the consent systems in the EU, 2011-2019

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

Table 3 below provides the linear regression model where the informed consent system is the independent variable, and the total number of deceased organ donors is the dependent variable. Model 1 provides the regression, including only the independent and dependent variables. Model 2, on the other hand, includes all covariates. Below the table, the R-squared and the adjusted R-squared results are provided. In these cases, Model 1 and Model 2 explain 19 and 38 percent of the variation, respectively. This means that including covariates makes the second model statistically stronger.

The regression table also reveals that the independent variable, which is the informed consent system, is statistically significant at the 95% significance level. Model 2 indicates that the informed consent system is associated with decreased organ donations. In addition to that, the coefficients of covariates (ICU beds per 1000 population, hospital beds per 1000 population, as well as healthcare expenditures as a % of GDP) are also statistically significant. The results reveal that a higher number of ICU beds per 1000 population and a higher number of hospital beds per 1000 population are associated with decreasing organ donation rates. However, these coefficients are low (-0.89 and -0.61), and the reason for a negative correlation is unclear.

Academic literature indicates that more ICU beds are crucial for creating opportunities for organ donation rates. Since most of the donors are patients who suffered brain death, a higher number of ICU beds ensures the necessary life support these patients need so that their organs could be transplanted (de Lange, Soares, and Pilcher 2020). Table 3 also indicates that a higher level of healthcare expenditures as a % of GDP is associated with higher organ donation rates (by 2.29 points). Coefficients of covariates of GDP pc, number of nurses per 1000 population, and Christianity are not statistically significant.

dependent variable - total number of deceased organ donors						
	Mod	el 1	Model 2			
	Coefficient	p-value	Coefficient	p-value		
Informed consent	-9.05	0.000***	-8.04	0.000***		
GDP_pc			0	0.676		
ICU beds			-0.89	0.070**		
Hospital beds			-0.61	0.062**		
Nurses			-0.41	0.147		
Christian			-1.93	0.257		
Healthcare						
expenditures			2.29	0.000***		
Intercept	22.39	0.000***	14.78	0.000***		
Signifi	cance levels:	·***' 0.05, ·	***' 0.01			
R-squared	0.19 0.38					
Adi R-squared	0.19 0.36					

Table 3. Regression table, informed consent and the deceased donation rates, 2011-2019

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

To attribute a certain level of variation and to observe the unobserved factors in the selected period, the time dummy variables were included in the regression models. Time dummies allow to better measure the effect of the informed consent system on organ donation rates when controlling for the factors we cannot observe, such as economic shocks. Table 4 below indicates that coefficients of time dummies are not statistically significant, meaning that they do not substantially affect organ donation rates in the informed consent system. Coefficients of adjusted-R squared remain the same as in Table 3, which means that the model with and without time dummies explain the same percent of the variation.

Table 4. Regression table, informed consent and the deceased donation rates, time dummies,

dependent variable - total number of deceased organ donors						
	Model	Mode	12			
	Coefficient	p-value	Coefficient	p-value		
Informed consent	-9.05	0.000	-7.69	0.000		
GDP_pc			0	0.715		
ICU beds			-0.85	0.087		
Hospital beds			-0.63	0.059		
Nurses			-0.53	0.066		
Christian			-1.73	0.312		
Healthcare expenditures			2.42	0.000		
year						
2012	0.65	0.791	-0.59	0.819		
2013	0.87	0.723	-0.2	0.935		
2014	0.93	0.705	-0.02	0.994		
2015	3.05	0.217	2.29	0.350		
2016	2.91	0.239	2.29	0.349		
2017	2.44	0.322	2.31	0.340		
2018	2.88	0.243	2.55	0.289		
2019	2.66	0.281	4.21	0.101		
Intercept	20.57	0.000	12.71	0.002		
Sign	ificance levels: '*	***' 0.05, ***	' 0.01			
R-squared		0.2		0.410		
Adj. R-squared		0.17		0.36		

2011-2019

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

The living organ transplantation rates were used to analyze further the informed consent system's effect (Table 5). Only transplantations of livers and kidneys were selected as these are the most common living transplantations (Scholz 2020). In addition, previous literature also analyzed the rates of transplantations of these two organs to indicate the association of the consent system on living transplantations (Abadie and Gay 2006; Arshad, Anderson, and Sharif 2019). Model 1 and Model 2 in Table 5 introduce the regression results with and without covariates. Looking at kidney transplantations, the adjusted R squared measure increases substantially from 18 to 65 percent when adding the covariates. That means that Model 2 explains 65 percent of the informed consent system's effect on the total number of kidney transplants. The independent variable and all covariates are statistically significant. The table indicates that the informed consent system is associated with a higher number of living

transplantations (by 6.46 points). In addition to that, a higher level of healthcare expenditures as a % of GDP is also associated with a higher number of living transplants (by 1.72 points).

On the other hand, higher numbers of ICU beds, hospital beds, and nurses are associated with lower rates of living kidney transplantations (in very modest numbers). Finally, it also indicated that being Christian negatively associates with kidney transplantation rates.

As for liver transplantation rates, the model explains only 11 percent of the variance, meaning that there are other unobserved variables associated with the number of liver transplants. Coefficients of GDP pc, hospital beds, and healthcare expenditures are not statistically significant. Furthermore, a higher number of ICU beds are only slightly associated with increased living liver transplantations. In contrast to kidney transplantation rates, being Christian correlates positively with a higher number of liver transplants.

dependent variable - total number of living transplantations								
		K	idney			Li	ver	
	Mo	del 1	Moo	iel 2	Moc	lel 1	Model 2	
	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value
Informed consent	6.46	0.000	5.35	0.000	-0.13	0.224	-0.25	0.077
GDP_pc			0	0.011			0	0.436
ICU beds			-0.71	0.006			0.11	0.032
Hospital beds			-0.33	0.054			0.01	0.701
Nurses			-0.47	0.002			0.01	0.631
Christian			-7.63	0.000			0.16	0.356
Healthcare								
expenditures			1.72	0.000			0.07	0.170
Intercept	4.82	0.000	2.78	0.137	0.41	0.000	-1.05	0.004
		Signif	icance level	ls: '***' 0.0	05, '**' 0.0	1		
R-squared		0.18		0.67		0		0.14
Adj. R-squared		0.18		0.65		0		0.11

 Table 5. Regression table, informed consent and living transplantations, 2011-2019

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

When scholars analyzed the effect of the informed consent system on organ donation and transplantation rates, they suggested excluding Spain from the analysis, as it could be treated as an outlier compared to other EU countries (Shepherd, O'Carroll, and Ferguson 2014). Table 6 illustrates the results of the regression model, which excludes Spain. On the left side of the table in the first two columns, results of regression analyses, including Spain with and without covariates, are provided. On the right side of the table, in the third and fourth columns of the table, results of regression analyses excluding Spain with and without covariates are provided. Adjusted R squared indicates that both models explain variance better with covariates than without them. The coefficient of the informed consent system variable in both cases (including/excluding Spain and with/without covariates) remains statistically significant. Also, in all cases, the informed consent system is associated with lower organ donation rates. A higher level of healthcare expenditures as a % of GDP in both cases associates with higher organ donation rates. Still, when Spain is excluded, the coefficient of the informed consent variable is lower (from 2.29 points to 1.46), meaning that excluding Spain from the model gives more accurate results.

dependent variable - total number of deceased organ donors											
	Including Spain						Excluding Spain				
	Mo	del 1	Mo	del 2	Model 1		Model 2				
	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value			
Informed consent	-9.05	0.000	-8.04	0.000	-7.88	0.000	-7.84	0.000			
GDP_pc			0	0.676			0	0.417			
ICU beds			-0.89	0.070			-0.37	0.366			
Hospital beds			-0.61	0.062			-0.11	0.679			
Nurses			-0.41	0.147			0.03	0.888			
Christian			-1.93	0.257			-3.04	0.033			
Healthcare											
expenditures			2.29	0.000			1.46	0.001			
Intercept	22.39	0.000	14.78	0.000	21.22	0.000	11.4	0.000			
		Signific	cance leve	els: '***' 0	.05, '**' 0	0.01					
R-squared		0.19		0.38		0.19		0.39			
Adj. R-squared		0.19		0.36		0.19		0.36			

Table 6. Regression table, informed consent and the donation rates, excluding Spain, 2011-2019

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

The regression analysis table below (Table 7) presents the living transplant rates of kidneys and livers, excluding Spain from the model. The results remain unchanged, as was also indicated in Table 5, which included Spain in the model and presented the associations between the total number of living transplantations and the informed consent system with and without covariates. Again, in both Table 5 and Table 7, the informed consent system is associated with a higher kidney transplantation rate. Coefficients of the informed consent system variable in the models of liver transplantations remain too low to make a conclusion about the associations. **Table 7. Regression table, informed consent and living transplantations, excluding Spain, 2011-2019**

dependent variable - total number of living transplantations								
		Kid	ney			Li	ver	
	Mo	odel 1	Model 2		Model 1		Model 2	
	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value	Coeff.	p-value
Informed consent	6.63	0.000	5.34	0.000	-0.13	0.253	-0.25	0.086
GDP_pc			0	0.016			0	0.368
ICU beds			-0.72	0.008			0.12	0.026
Hospital beds			-0.34	0.057			0.02	0.595
Nurses			-0.48	0.003			0.02	0.486
Christian			-7.6	0.000			0.14	0.417
Healthcare								
expenditures			1.73	0.000			0.06	0.283
Intercept	4.65	0.000	2.86	0.140	0.4	0.000	-1.09	0.003
R-squared		0.19		0.67		0		0.15
Adi. R-squared		0.19		0.65		0		0.11

Source: compiled by the author. Greece is excluded from the analysis as it changed the system during the selected period. Statistically significant variables are marked in grey color.

Empirical results

Five different types of models analyzing the association between organ donation and transplantation rates were constructed: (1) using the deceased organ donation rates and informed consent system variables with and without covariates (Table 3), (2) using the deceased organ donation rates and informed consent system variables including the time dummies (Table 4), (3) using the living organ transplantation rates and informed consent system variables with and without covariates (Table 5), (4) using the deceased organ donation

rates with and without covariates excluding Spain as an outlier from the model (Table 6), (5) using the living organ transplantation rates with and without covariates excluding Spain as an outlier from the model (Table 7).

All models which included the deceased organ donation rates as the dependent variable revealed that the informed consent system is associated with a lower number of deceased organ donations. By including the covariates in all cases, the reliability of the models increased (with higher adjusted R-squared indices). That means that the variation of the models is better explained with covariates than without them. As for the time dummies, they are statistically insignificant when eliminating the unobserved factors over the years. The hypothesis (H1) that the informed consent system is associated with lower deceased organ donation rates is accepted. The results align with the Abadie and Gay (2006) study. They also found that the informed consent system leads to a smaller number of total deceased organ donations (by 25-30%). However, the results contradict the findings of Arshad's recent study on OECD countries (2019). In a 2019 study, scholars did not find a statistically significant relation between the consent system and organ donation rates.

Results concerning the living transplantations rates partly align with the findings in the academic literature (Sharif 2018; Horvat et al. 2010). The regression models in this thesis indicated that the informed consent system is associated with higher rates of living kidney transplantations. On the other hand, higher rates of liver transplantations are not associated with the informed consent system. In other words, countries with a presumed consent system have lower living organ donation rates only for the cases of kidney transplantations. Therefore, the hypothesis (H2) stating that informed consent countries are associated with higher living transplantation rates can only be accepted in the case of living kidney transplantations.

In all five models, the coefficients of all covariates (except for Christianity and healthcare expenditures as a % of GDP variables) are too low to make any substantial

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associations regarding organ donation and transplantation rates. Even though the coefficients of covariates of GDP per capita, number of ICU beds, and number of hospital beds proved to be statistically significant, they are too low to make robust estimates. Additional data is needed to find the correlation between these three variables and organ donation and transplantation rates.

Furthermore, the Christianity variable, which indicated if the prevailing religion in an EU country is Christianity, was associated with lower organ donation rates. The results contradict the findings in academic literature since Christianity is related to altruism; therefore, the inclination to donate should be higher in Christian societies (Bresnahan and Mahler 2010). However, the results of this study reveal that the correlation between Christianity and organ donation or transplantation rates is only statistically significant when Spain was excluded from the regression model. In both - the deceased organ donations and the living organ transplantations - models, Christianity is associated with lower donation rates. The results of this thesis, which indicate that being predominantly Christian is not associated with higher donation rates, could be partly explained by the inclusion of data from rather conservative EU societies into the model. For instance, in the cases of Lithuania or Latvia, the church sees the body as an indivisible object created by God; thus, it considers that organ donation or transplantation should not be allowed even after death (CIVICUS 2021; Human Rights Monitoring Institute 2021; Mustillo 2018). Even though the modern Catholic Church has been supporting organ donation and transplantation since 1895 (Donor Alliance 2022), some countries' religious leaders do not follow Vatican's lead.

Lastly, a higher level of healthcare expenditures as a % of GDP is associated with higher rates of deceased organ donations and higher rates of kidney transplantations. However, the coefficients are too low to make any substantial associations.

There has been a lot of literature in the fields of psychology, economics, and public policy on the role of presumed vs. informed consent donor systems on organ donation rates. This analysis has added several significant findings to the already conducted research.

Firstly, unlike other studies, this analysis included many covariates which indicate the quality of the healthcare system (ICU beds, hospital beds, nurses, healthcare expenditures). This allowed to measure whether it is the quality of the healthcare system or whether it is the existence of a particular consent system that has stronger associations with higher donation rates. The four indicators were selected according to already conducted quantitative analyses on organ donation rates (Arshad, Anderson, and Sharif 2019; Abadie and Gay 2006; Shepherd, O'Carroll, and Ferguson 2014) as well as the qualitative research about the success cases of Wales and Spain (Noyes et al. 2019; Sharif 2017; Matesanz, Domínguez-Gil, et al. 2017). As previously mentioned, the selected covariates were statistically significant in most cases; however, the correlating coefficients were very low. That could be explained by the Noyes et al. (2019) study findings which concluded that a higher number of nurses and higher healthcare expenditures are not enough if there is no available data on the number of specifically trained nurses nor on the transplantation and donation coordinators' numbers.

Secondly, even though the analysis period was different (more up-to-date) from previous research papers, this thesis's results partly contradict the conclusions of the most recent quantitative study by Arshad et al. (2016). They stated that most of the previous quantitative research on the topic of organ donation and transplantation rates used data that was too homogenous and was also old, which could alter study results. Contrary to Arshad et al. (2016) conclusions, the results of this thesis align with the findings of other previous studies. These studies found a correlation between the presumed consent system and higher organ donation rates. Ultimately, by analyzing the newest data available up to the year of 2019, this thesis rejects the Arshad et al. (2016) study conclusions regarding the data homogeneity.

Possible limitations

The empirical results should be considered in the light of the following limitations:

Firstly, the sample contains only the European Union countries and is very homogenous. Only 6 EU countries have an informed consent system. Even though this sample is suitable to draw the recommendations for the EU policymakers, it makes it harder to generalize the results and adapt to other countries which are outside of the region. Additional analysis, including other countries, is necessary.

Secondly, certain correlations from the pooled OLS regression analysis are difficult to explain without additional research. For instance, it is unclear why the higher number of ICU/hospital beds or the higher number of nurses is associated with lower numbers of organ donations and transplantations. It could be that the omitted variable bias occurred in the correlation of the dependent variable and selected covariates. Further qualitative analysis or inclusion of other covariates would help to explain this uncertainty.

Thirdly, the data availability was limited. Thus, the data was not collected from a single source, which could be why certain indicators are accounted for differently. For example, in the case of nurses, certain datasets included a number of nurses and midwives while others only included the number of nurses. Also, for some countries, the covariates' data (such as the number of nurses or ICU/hospital beds) was provided for the total population, and the author herself made the calculations for the 1000 population.

Additionally, a more advanced model might improve the results, for instance, by using the difference in differences or the two-way fixed effects methods. This would allow to measure the impact of the change of the consent system and not only the associations of the informed consent system with the donation rates. This would add more clarity to the findings. Lastly, the thesis studied the associations between the informed consent system and the organ donation and transplantation rates. The presented associations do not lead to causal inferences. Although this thesis contributed to understanding the associations by including covariates that were previously not included in other studies (e.g., hospital beds), the design of this study is limited in suggesting policy changes.

Conclusions and policy recommendations

Conclusions

The paper empirically analyzed whether there is an association between the informed donor consent registry system and the higher rates of 1) donations of deceased organs and 2) living kidney and liver transplantations. The chosen research period is 2011 and 2019 and includes all the European Union countries.

To examine the effect, a comprehensive country-level panel database was built using various available sources, including the Global Observatory on Donation and Transplantation (GODT), Statista, The Global Economy, the World Bank, and the countries' internal statistics portals.

A panel pooled ordinary least square regression was conducted with time dummies to see whether any unobserved factors influence organ donation and transplantation rates. As all time dummies were statistically insignificant, they did not influence the findings. In addition to that, it was found that the informed consent system, prevailing in 6 of the EU countries, is associated with lower deceased organ donation rates (by 9.06 points) and higher living kidney transplantation rates (by 6.64 points). Spain was excluded from two separate models to test if this outlier case would influence the results of the regression. In both models, where the deceased organ donation and living organ transplantations were dependent variables, the results did not differ when Spain was excluded. Furthermore, covariates that were included explained the variance better (higher adjusted R squared indices). However, the regression analysis revealed that there is only a minor association between a higher number of ICU/hospital beds or a higher number of nurses and higher organ donation and transplantation rates. Surprisingly, this thesis revealed that the countries where Christianity is the dominant religion are associated with lower deceased organ donation rates (up to 7.63 points). It challenges the assumptions

found in the academic literature that Christianity is related to altruism; therefore, it would be expected that in predominantly Christian societies, donation rates would be higher.

The results of this thesis identified further research areas. More variables corresponding to the quality of the healthcare system could be included in order to further analyze the effect of the consent system on organ donation and transplantation rates. As the findings of this research indicate, the coefficients of ICU/hospital beds, nurses, and healthcare

expenditures as a % of GDP covariates are very low; further research is needed to indicate other variables which could measure the quality of healthcare systems. Moreover, the difference in differences or the two-way fixed effect methods could be used to calculate the impact of the change in the consent system. Lastly, the analysis of the effect of the informed consent system could be extended to other regions to see if the same results appear and whether policy recommendations could be generalized.

This thesis substantially contributed to the existing literature concerning the effect of the consent system on organ donation and transplantation rates. 1) This thesis included more covariates that measure the quality of the healthcare system to test whether it is the consent system itself or whether it is the quality of the healthcare system that affects the organ donation and transplantation rates. Results revealed, however, that different covariates which measure the quality of the healthcare system are only weakly correlated with the organ donation and transplantation rates. 2) This paper analyzed the EU region exclusively. EU has its separate plans on how to increase the organ donation and transplantation rates in MS, as well as it has a unified policy on the quality and safety of donated organs. Thus, the targeted policy recommendations for the EU policymakers could be provided. 3) It developed a comprehensive country-level healthcare database. 4) It found that the selection of the research period does not affect the results of the association between the informed consent system and the lower organ donation rates.

Policy recommendations

The literature analysis revealed contradicting results on whether the consent system increases or decreases organ donation and transplantation rates. However, scholars agreed that the switch of the consent system alone is not enough and must be done together with other improvements. Although some countries are reluctant to switch to the presumed consent system because of different beliefs, some recommendations could be universally applied. The recommendations are primarily drawn from the analysis of the success cases of the Spanish and the Welsh models and this thesis' empirical findings. Investments in education, training, and infrastructure are the three main policy points.

- 1. The introduction and training of the special nurses working in the ICU with the patients' relatives before the patients are dead are crucial.
- 2. The transplantation coordinators should be available 24/7 and should work in every hospital.
- 3. Change from the informed to presumed consent system should be considered, as it is associated with higher rates of deceased organ donations. The number of deceased organ donations has a significantly higher share of the total number of donations compared to living organ transplantations. Additionally, according to the literature analysis, the system change is not considered costly and certainly does not negatively impact the donations rates.
- 4. To increase the rates of living organ transplantations and deceased organ donations, targeted communication campaigns for the general public must be organized every year. That would allow to educate people about the importance of organ donation regardless of the existing consent system.

Appendix 1: Organ Donation System in the EU

Country	Organ Donation System, 2022
Austria	Presumed
Belgium	Presumed
Bulgaria	Presumed
Croatia	Presumed
Cyprus	Presumed
Czech Republic	Presumed
Denmark	Informed
Estonia	Presumed
Finland	Presumed
France	Presumed
Germany	Informed
Greece	Presumed
Hungary	Presumed
Republic of Ireland	Informed
Italy	Presumed
Latvia	Presumed
Lithuania	Informed
Luxembourg	Presumed
Malta	Informed
Netherlands*	Presumed
Poland	Presumed
Portugal	Presumed
Romania	Informed
Slovakia	Presumed
Slovenia	Presumed
Spain	Presumed
Sweden	Presumed

Source: compiled by the author using (Scholz 2022) and checking every country's national transplantation information available in official sources or other academic papers. A list of sources of all systems is available from the author on request.

sources of all systems is available from the author on request. *the Netherlands changed their system to presumed in 2020. As the analysis included the data for 2011-2019, it is the 7th informed consent country.

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