The Toll of COVID-19 on Organ Donation and Kidney Transplantation in Europe: Do Legislative Defaults Matter?

Abstract

This study investigates the cascading effects of COVID-19 pandemic on organ donation and transplantation in Europe. We also check whether legislative defaults for organ donation have a role in these outcomes. For this purpose, we used data from 32 European countries, between 2010-2021, and estimated pooled OLS regressions. We find that COVID-19 pandemic reduced deceased organ donation rates by 23.4%, deceased kidney transplantation rates by 27.9% and live kidney transplantation rates by 31.1% after accounting for health system capacity indicators. While our study finds that presumed consent legislation under normal circumstances leads to notable benefits in terms of deceased kidney transplantation and organ donation rates, the legislative defaults did not have a significant impact during the pandemic. Additionally, our findings indicate a trade-off between living and deceased transplantation that is influenced by the legislative default.

Keywords: COVID-19, organ donation, transplantation, presumed consent, consent regime

1. INTRODUCTION

The COVID-19 outbreak put unprecedented strain on the healthcare systems all around the world. According to the WHO survey of 155 countries prevention and treatment services for non-communicable diseases (NCDs) have been severely disrupted since the COVID-19 pandemic began.[1] These disruptions could affect patients with organ failure. Several countries experienced a sharp reduction in organ donation and transplantation activity, especially during the early phase of the pandemic, including India[2], Israel[3], Italy[4], the Netherlands[5], South Korea[6], Spain[7], the United Kingdom[8], and the United States[9]. An inverse relation between SARS-CoV-2 infections and overall solid-organ transplantation has also been found in the USA and France[10]. However, after the dramatic first and second waves hit, some countries developed ways to deal with dwindling donor pool and health system strain over time.[11,12] As a consequence, some countries increased transplantation figures after the first wave to around normal activity.[13]

Multiple pandemic related factors could affect organ donation and transplantation from both the demand and supply sides. Firstly, transplant societies recommended suspension of live kidney transplantation and higher precautions in accepting kidney transplantation, especially in the first months after the start of the pandemic[14]. Secondly, the strain on healthcare systems can leave less room for dealing with organ donation and transplantation (ODT).[15] In several countries, surgical units and intensive care units (ICUs) were converted into COVID-19 ICUs, leading to a decrease in available ICU beds for organ donors.[16] Yet, to a certain extent, healthcare systems can cope with adverse circumstances. In Germany, the pandemic did not impair the transplantation performance at the end of May 2020.[17] It is also reported that because of extensive stay-at home orders, traumatic brain injuries because of road traffic accidents decreased and many potential donors died at home without reaching hospital, both factors leading to a shard drop in brain death donors.[4,18] Even when patients died at the hospital, protective measures limited face-to-face interactions

between transplant teams and relatives, leading to fewer family approaches.[3] With regard to demand, patients with organ failure and organ recipients might be more adversely affected from COVID-19 disease[19-21] which could slightly reduce (or postpone) the need for organs. For example, Italy reported a 15% drop in kidney waiting list patients, however no reduction was observed for liver and heart waiting lists.[22]

So far, numerous studies have looked at the impact of the COVID-19 pandemic on organ donation and transplantation activity in a single country or in a small number of countries. Some multi-country studies have compared, for example, COVID-19's economic impact on healthcare facilities and systems[1], policy responses and related factors[23], the effect of the first wave on all-cause mortality in 21 industrialized countries[24], or the impact of the pandemic on all-cause mortality in 40 industrialized countries and US states prior to mass vaccination.[25] Other studies explored the impact of COVID-19 on heart transplantation in Asia and Oceania[26], its global impact on liver transplantation practices[27], and more generally on organ transplantation rates and its effects on waitlisted patients in 22 countries worldwide.[13] However, to our knowledge, no study measured the toll of COVID-19 on organ *donation* rates beyond one or a few countries, compared the differential impact of the severity of the pandemic on organ donation in different countries, or assessed the possible mediating effect of government responses, health care capacity, and health policies. To our knowledge, this is the first study to analyze such relationships beyond a single country.

Although many studies in the last decade have explored the potential impact of opt-in (explicit consent) and opt-out (presumed consent) laws on organ donation rates, no consensus has been reached to date [28-33]. By acting as a nudge, among other psychological and behavioral effects on potential donors and their families, defaults could be responsible for the differential impact of opt-

in and opt-out on organ donation rates (for a quite comprehensive review on this issue, see Steffel et al. 2019[34]). Most of the empirical studies are based on international comparisons of organ donation rates by consent legislation in normal times. What lessons can we learn from the current health crisis?

The international variability in COVID-19 death toll, vaccination policies and strain on healthcare systems, as well as in government's measures to address it, offers a unique opportunity to explore the potential differential impact of consent legislation in times of crisis, i.e. whether, how and to what extent policy defaults can mediate the impact of the pandemic on organ donation and transplantation rates.

The COVID-19 crisis could also exert its own influence on people's attitudes and behaviors towards organ donation. By making the possibility of death present, the pandemic may have prompted people to think about organ donation for the first time and to tell their loved ones about it. It could affect people's views of the healthcare system and healthcare professionals, exacerbating feelings of trust/distrust or fear/support. It is also known that when people consume their willpower for dealing with challenges, they are less likely to show altruism in a subsequent task.[35,36] As the pandemic has brought many circumstances that can easily deplete one's resources for altruism, we could expect a decrease in the willingness to donate, especially in opt-in countries where individuals have to go the extra mile by registering their consent. On the other hand, disasters also enable heightened feelings and acts of altruism[37] and may therefore have a positive impact on organ donation.

In this study, we use data from two sources, the International Registry in Organ Donation and Transplantation (IRODaT) and the Global Observatory on Donation and Transplantation (GODT). We consider deceased organ donation (DOD) rates for all organs per million people (pmp). We

also consider deceased kidney transplantation (DKT) rates pmp, in particular, as well as live kidney transplantation (LKT) rates pmp. We use control variables for each country to capture the possible mediating effect of other factors, such as healthcare capacity, severity of COVID-19, and government responses. In addition, to better assess the evolution of organ donation and transplantation during the pandemic compared to previous years, we use data from 2010 to 2021. To our knowledge, this is the longest period of data that has been considered for this type of study.

2. MATERIALS & METHODS

To identify the impact of COVID-19 pandemic, firstly, we need to test whether there is change in organ donation and organ transplantation figures over time. To capture the possible moderating effect of the severity of the pandemic and the impact of presumed consent legislation, we run five regression models, progressively adding the variables of interest, as outlined in Equation 1

$$OD_{i,t} = \alpha_0 + \alpha_1 Pan_t + \alpha_2 Pan_t * SP_{it} + \alpha_3 PC_{i,t} + \alpha_4 Pan_t * PC_{i,t} + \beta X_{i,t} + u_{i,t} \dots\dots\dots [1]$$

OD represents log of organ donation or transplantation indicators for country i, at time t, Pan represents the pandemic and takes value 1 in year 2020 and 2021, 0 otherwise. SP stands for the severity of the pandemic indicator in country i at time t. PC represents dummy variable for legislative defaults for country i, at time t and X is a vector of control variables such as health expenditure per capita, medical doctors per capita, and hospital beds per capita.

As the dependent variables are continuous, pooled OLS regression models are utilized. In our analysis period, the legislative defaults on deceased organ donation remains relatively stable over time. Thus, it is not possible to incorporate country-specific factors into our regression models and accurately estimate the impact of the presumed consent variable.[38] Yet, we also consider the possibility of significant country fixed effects. We followed Abadie and Gay[39]'s approach to run a generalized Hausman specification test. That is, we test whether there is any evidence for the

existence of time-invariant factors in the regression models or not by comparing the coefficients of time-varying variables in country-fixed effects specification and the pooled OLS specification. The underlying intuition is that if there are significant country fixed effects, the coefficients of all the variables in country fixed effects specification will be unbiased, but they will be biased in the pooled OLS specification. We test whether there are significant differences in time varying variables such as health expenditure per capita, medical doctors per capita, hospital beds per capita and pandemic dummy variable, between the pooled OLS and country fixed effects models. Moreover, we also added a set of control variables in regression models to account for potential differences between countries.

To obtain percentage interpretation of the effect sizes, logarithmic of the dependent variables are taken. Mathematically, the log approximation works well to show percentages when the coefficient is less than 0.2. When the coefficients (β) are larger than 0.2, the log correction is executed by the following formula: exp(β)-1.

2.1. DATA

For this study, we obtained data from IRODaT (International Registry in Organ Donation and Transplantation) between 2010 and 2021 for 32 countries in Europe. The metrics we investigate are deceased organ donation (DOD) per million people (pmp), deceased kidney transplantation (DKT) pmp and live kidney transplantation (LKT) pmp. DOD is chosen to show the overall impact in a broader context and we choose to focus on deceased and live kidney transplantation as kidney transplantation is the most common transplantation operation. Therefore, data for kidney transplantations are more readily available. Although there are transplantations for other organs in some countries as many countries do not consistently report or make the operations of other organs. We also use number of DOD, DKT and LKT as a robustness check.

To study the impact in Europe, we use the Council of Europe (CoU) membership as our sample inclusion criteria. We could not include Albania, Bosnia and Herzegovina, Liechtenstein, Montenegro, North Macedonia, Vatican, Monaco, Ukraine and Serbia in the sample countries as their organ donation and transplantation figures were not consistently available in IRODaT webpage. Russia was a CoU member, however its donation indicators was not available for 2021. Therefore, we excluded Russia as well. Our sample is composed of data from the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom. When the data is not available in IRODaT, we used the corresponding values from Newsletter Transplant [40] collected by Spanish Organ Donation Agency (ONT).

The information regarding legislative defaults are obtained from Morla et al (2021)[41]; Deldago et al (2019)[42]; Ugur (2015)[29]. We treated both the UK and the Netherlands as presumed consent countries for year 2020 as England and the Netherlands has switched to presumed consent legislation as of 20th of May and 1st of July, 2020, respectively.

As a measure of health care system capacity, we utilize hospital beds per 100,000 people from EUROSTAT's webpage. The missing values are replaced by available values from World Development Indicators database. Another measure for health care system capacity is medical doctors per 10,000 people gathered from WHO's webpage. Current health expenditure (CHE) per capita in PPP is also used as a measure for healthcare spending. This metric is obtained from WHO's webpage. When the values are missing in data sources, the same rates are assumed for all the variables.

COVID-19 cases pmp and deaths due to COVID-19, pmp are used as a measure of the severity of the pandemic. These numbers are obtained from John Hopkins University COVID-19 database. We also used COVID-19 Government Response Tracker data.[43] This dataset provides different indices for the measures governments take in response to COVID-19 outbreak in various domains. We utilized the overall response index which gauges the strength of government measures and the containment and health index which essentially measures health system policies such as the COVID-19 testing regime, emergency investments into healthcare and vaccination policies.

3. RESULTS

To explore the impact of the COVID-19 pandemic, in Figure 1 Panel A, we provide how some organ donation indicators (DOD pmp, DKT pmp and LKT pmp) change over time. We can clearly see a drop in 2020 and some but not full recovery in 2021 in all indicators. Appendix Figure A-1 shows the number of DOD, DKT and LKTs. We see the same pattern of a sharp drop in 2020 and some but not full recovery in 2021 according Figure A-1, too. To have a more concrete sense of change in each country, in Appendix Table A-1, the number of deceased organ donations (DOD) and DOD, pmp for 2019, 2020 and 2021 in our set of countries are provided. Table A-1 also shows the presumed and informed consent countries in our sample.

Figure 1 about here

To explore the COVID-19 pandemic's potential differential impact by consent legislation, in Panel B of Figure 1, we provide DOD pmp, DKT pmp for informed and presumed consent countries. It is clearly seen that DKT pmp and DOD pmp is higher in presumed consent countries compared to informed consent countries before and during the pandemic. Again, in both group of countries, there are marked reductions in year 2020 and rates starts to recover in 2021 but it is far from full recovery regardless of legistation type. Appendix Figure A-2 shows the number of DOD

and DKT for informed and presumed consent countries. We see a very sharp drop for informed consent countries in 2020 in Figure A-2.

Table 1 about here

Table 1 shows descriptive statistics for our sample. We divided countries based on their legislative default and the pandemic status. Mean values and standard deviations for presumed and informed consent countries before the pandemic are shown in column 1 and 2, whereas mean values and standard deviations for both country groups during the pandemic are shown in column 3 and 4, respectively. Significance stars in the second and fourth columns show the t-test results that checks the statistical significance of the differences between presumed and informed consent countries before the pandemic and during the pandemic.

Presumed consent countries have on average 20.43 DOD pmp which is significantly higher than 14.18 DOD pmp in informed consent countries rates before the pandemic. We observe the same pattern for DKT. DKT pmp is significantly higher in presumed consent countries, Concerning LKT, informed consent countries fared better before the pandemic in terms of per capita live kidney transplantations compared to presumed consent countries and these differences are statistically significant.

When we look at the health system indicators before the pandemic, informed consent countries had significantly higher health expenditure per capita, whereas presumed consent countries had significantly higher hospital beds per capita and slightly higher medical doctors per capita.

Comparing the columns 3 and 4 shows that presumed consent countries have significantly higher organ donation pmp and informed consent countries have significantly higher live transplantation pmp and all other differences between presumed and informed countries has disappeared during the pandemic. These results can stem from the pandemic's disproportionate

effect on presumed consent countries. According to Table 1, presumed consent countries have slightly higher COVID deaths per capita than informed consent countries. But, the differences are rather modest and not statistically significant.

Table 2 reports regression estimates. The first 5 models show the results for the log of DOD pmp, the dependent variable in the second 5 and bottom 5 models is the log of DKT pmp and the log of LKT pmp, respectively. To see whether the pandemic affects organ donation and transplantation indicators, Model 1, 6 and 11 shows the coefficient of pandemic dummy variable. The rest of the coefficients (health system indicators) are provided in Appendix Table A-2. Firstly, we discuss the specification test results that compares the country fixed effects model with the pooled OLS model. P-values are all markedly above 0.05 which suggests no significant difference for the time varying coefficients between the pooled OLS and the country fixed effects specifications. This evidence supports the validity of the pooled OLS results.

According to model 1, the COVID-19 pandemic caused 23.4% drop in deceased organ donation rates (how log correction is executed is explained in the materials and methods section). This effect is statistically significant at 5% significance level. According to Model 6 for deceased kidney transplantation, we observe 27.9% drop during the pandemic. When we examine the impact of the pandemic on live kidney transplantation rate, there is a 31.1% fall in live kidney transplantation pmp according to Model 11.

Table 2 about here

In Model 2, 7 and 12, regression results for the impact of presumed consent legislation are provided. According to Model 2 and 7, after taking into account the presumed consent legislation and other controls, the pandemic leads to 28% and 30.5% reduction on DOD and DKT, pmp respectively. The regression results show a substantial advantage of presumed consent legislation

in terms of DOD and DKT as the coefficient of presumed consent is large and statistically significant in all of the models. The interaction of pandemic with the presumed consent legislation is positive in all the models in Table 2, albeit statistically not significant.

To see whether the severity of the pandemic, the degree of government response alters the organ donation and transplantation performance, the last 3 models of both DOD and DKT show the interaction term of the pandemic with COVID deaths per capita, the overall government response and the health containment measures, respectively. We do not detect any negative impact of the severity of the pandemic or the stringency of government responses on organ donation and deceased kidney transplantation.

From Table 1, one can easily discern that informed consent countries have higher live organ donation rates and number of live transplantations before the pandemic as well as during the pandemic. Moreover, according to models of Table 2, presumed consent countries have around 42% lower live kidney transplantation rate after controlling for health system capacity indicators. That is, a clear pattern emerges that shows a substantial advantage of informed consent countries in live organ transplantations.This finding suggests a trade-off in informed consent countries. As individuals in these countries were not able to find sufficient deceased organ donation, they seem to seek a live donation. Secondly, according to Model 13 in Table 2, the severity of pandemic does not have a significant impact on live transplantations. Yet, according to Model 14 and 15, the overall government responseand health containment policies are found to be associated with higher live donations.

Luxembourg, had zero deceased kidney transplantation in some years. Similarly, countries with small population such as Luxembourg, Malta and Slovenia had zero live kidney transplantation rate in some years, therefore, taking log resulted in missing value. We check

whether the results stay robust to level form specification rather than log specification provided in the main results. Appendix Table A-3 provides the robustness check results. In line with our main results, we find a substantial and significant drop in DOD, DKT and LKT rates. DOD rates dropped by 3.2 points after taking into account health system control variables where before the pandemic the average DOD pmp was 18.36. DKT and LKT pmp dropped by almost 5.6 and 2.1 points, respectively. The average DKT and LKT pmp before the pandemic was 27.89 and 8.47, respectively.

As both the Netherlands and the UK changed their legislation in 2020, we also checked whether categorizing the Netherlands and the UK as informed consent countries changes the results and the results are robust to that specification, too (Appendix Table A-4).

4. DISCUSSION

A previous study has shown how COVID-19 affected organ transplantation and waitlisted patients (i.e. the demand side) over time during the first year of the pandemic in 22 countries.[13] Here we examine how it affected organ donation (i.e. the supply side), as well as deceased and live kidney transplantation, during the same period in 32 countries while considering the mediating effect of several factors. Moreover, most of previous studies report early impact of the pandemic whereas our results are based on end of year data which can present a more accurate picture of the pandemic. Overall, our results show that COVID-19 caused a reduction of 23% in deceased organ donation rates (DOD), 28% in deceased kidney transplantation rates (DKT), and 31% in live kidney transplantation rates (LKT).

Firstly, the results show that the pandemic exacerbated the challenges of people with chronic organ failure. These results can stem from changes in demand and/or supply of organs. As the health systems were under strain, they might not have the resources to allocate to securing organ donation. At the same time, people who qualify to be organ donors or their relatives may be

reluctant for organ donation. The reason could also be that the pandemic brought additional loads to people's everyday life. Even if there was a temporary rise in altruistic acts at the beginning of the pandemic[44], the results imply that ego-depletion effect overrides the pandemic-driven-solidarity effect.

According to Table 2 and Appendix Table A-3, the drop for deceased kidney transplantation rate is larger than the drop for deceased organ donation rate. That is, not even every donation was used for transplantation. This is an indication of the strain on health care system capacity. Moreover, live transplantation rate decreased sharper than deceased kidney transplantation rate. This could be an indication of people's reluctance for donating and/or receiving organs as in live donation, there is a higher risk (both donors and recipients face the risk of catching COVID in hospitals during a transplantation). Indeed, there is evidence supporting higher mortality risk for organ transplantation recipients after catching COVID-19.[20,45].

The impact of COVID-19 on deceased organ donation and deceased kidney transplantation is not altered by the severity of the pandemic and the government response measures. The results might stem from transplant societies recommendation to take higher precautions[14] being applied all over the Europe regardless of the severity of the pandemic. Many countries COVID-response was "to follow the crowd" and in retrospect, these measures to fight the pandemic is seen by some researchers as excessive.[46]

Yet, there is some evidence that government responses to the pandemic was useful for increasinglive kidney transplantation rate. A strong government response captures resilience of the government to deal with the pandemic. The containment and health measures index include testing policies, contact tracing, short-term investments in medical services and vaccines.[43]As strong overall response or health response can free up the strain on the healthcare system a bit, these

resources might have been used to enable other life-saving medical interventions such as transplantations. Although both live and deceased tranplantation require extensive coordination of many healthcare professionals and institutions,[47] for a successful transplantation from deceased there is additional time constraints. Because kidneys are only viable for transplantation for a period of 48 to 72 hours after their removal from the deceased, they have to be transferred to the recipient very quickly.[48] These time constraints make coordination a lot more harder in deceased transplantation. Therefore, the government response to the pandemic may be too minor to influence the complex necessities of deceased organ transplantation, but to some extent could impact live kidney transplantation.

One novel result is that informed consent countries fare better than presumed consent countries in term of live transplantation. We find a clear advantage in deceased organ donation and deceased kidney transplantation in presumed consent countries which has been reported in many other studies.[29,39,49] The reason could be that as informed consent countries could not secure sufficient deceased organ donation, individuals had to find a live donor. This indicates a trade-off between deceased organ donation and live donation depending on the consent system. This finding can explain the mechanism through which informed consent countries cope with high organ demand to some extent. This can also explains why some informed consent countries did not switch to presumed consent regime.

The presumed consent does not have significant impact on countries' organ donation performance during the pandemic. It is known that organ donation has been affected by many factors such as whether routine family consent is sought[49], people's religious concerns about permissibility of organ transplantation[50], and many others[51]. Indeed, many studies highlight the fact that legislative defaults are only useful when combined with a well-functioning organ donation

system (See Etheredge [32], Steffel, Williams, Tannenbaum [34]). Thus, presumed consent legislation should not be seen as a silver bullet.

One limilation of our study is that we focused on European countries because they have similar health systems however, the COVID-19 pandemic severly affected many other countries.

5. CONCLUSION

This study represents the first cross-country comparative investigation to explore the impact of COVID-19 on both organ transplantation and organ donation rates while taking into consideration the mediating influence of government responses, health care capacity, and health care policies. We find that the COVID-19 pandemic caused a large burden on patients in need of organ donation overall by substantially reducing organ donation, deceased and especially live kidney transplantation rates. While our findings on the impact of the pandemic are consistent with prior research, our study expands upon previous work through a more comprehensive analysis that utilizes year-end data in 32 countries, providing a more precise depiction of the pandemic's impact.

Our investigation reveals that the decline in the rate of kidney transplantation from deceased is more pronounced than the reduction in the rate of deceased organ donation. The results show that, although presumed consent legislation, under normal circumstances, provides a significant overall advantage in deceased kidney transplantation and deceased organ donation rates, the legislative defaults did not have a significant effect during the pandemic. Our findings also suggest a trade-off between transplantation from deceased and living that depends on the legislative default.

In the event of a new health crisis, policymakers should take into account the impact of their measures on organ donation and transplantation rates and ensure that they do not exacerbate the

existing challenges faced by individuals with chronic organ failure. This will require close coordination among different healthcare sectors and policymakers.

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