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Does implementing opt-out solve the organ shortage problem? Evidence from a synthetic control approach*

Selina Schulze Spuentrup†

November 2023

Abstract

In light of the persistent shortage of organ donations needed to save precious human lives, several countries have modified their organ donation laws introducing an opt-out system. Using a panel dataset covering a 21-year period, I apply a synthetic control approach to focus on countries that changed their prevailing organ donation legislation from opt-in to opt-out. I compare them to a synthetic counterfactual from countries that have kept their legislation the same since 1999. Synthetic control estimates show that Argentina and Wales achieved substantially higher organ donation rates with the shift from an opt-in to an opt-out system than without the reform taking place. My findings suggest that as one strategy among others, implementing opt-out cannot solve the organ shortage problem entirely but effectively contributes to reducing it considerably.

Keywords: organ donation, opt-out, opt-in, presumed consent, informed consent, synthetic control method

JEL: I18, D78, E71

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1 Introduction

From the beginning of organ transplantation, countries have sought to increase the number of life-saving organs donated. In particular, some countries have changed their organ donation legislation to make every deceased a potential organ donor unless the person has objected. Using the variation in the two cases of Argentina and Wales, I examine whether these countries could effectively achieve higher organ donation rates by switching to an opt-out system.

Countries' legislation differs essentially in handling a situation where the deceased's will regarding organ donation is unknown. In opt-in countries, organ removal is only permitted if the potential organ donor has explicitly agreed during his or her lifetime. In contrast, in opt-out countries, anyone who has not objected can become an organ donor.[1] In 'hard' systems, next of kin are not involved in the decision-making process, whereas in 'soft' systems they are. Differences in the latter exist in whether close relatives are always consulted and even have the right to overrule the deceased's decision or whether close relatives are only consulted if no decision by the potential organ donor is known and are asked to decide instead (Rithalia et al., 2009; Douglas and Cronin, 2015). Organ removal is allowed in soft opt-in countries if the next of kin consent to organ donation and in soft opt-out countries if they do not object.

All over the world, more than 366 000 patients are currently waiting for a life-saving organ donation (Domínguez-Gil, 2022). In addition, more new patients are registered on the waiting list each year than organ transplantations can be realized. This inevitably leads to a growing shortage of cadaveric organs. Longer waiting times can substantially affect patients' quality of life or even lead to deaths while waiting. Mocan and Tekin (2007) estimate the total value of life lost due to a lack of organ supply to be approximately $4.8 billion in the U.S. only. Worldwide, about 27 000 people died on the waiting list in 2021 (Domínguez-Gil, 2022). Besides, there are beneficial effects for those who receive an organ. For instance, nearly 2.3 million life years were saved in the U.S. over 25 years (Rana et al., 2015). Transplantations are also cost-effective treatments, especially in renal replacement therapies, as kidney transplantation results in significant healthcare cost savings compared to dialysis (e.g., Karlberg and Nyberg, 1995; Laupacis et al., 1996; Jarl et al., 2018).

Despite some efforts of governments to promote awareness and willingness to donate among the population, ultimately, organs donated after death are not available in sufficient numbers to allow for all the transplantations needed. This is also due to the large difference

[1] Instead of opt-in and opt-out, the terms 'informed consent' and 'presumed consent' are likewise used analogously in the literature.

between expressed preferences and actual donation behavior. According to representative survey data, far more respondents declare their willingness to donate organs after death than have an organ donation card or have registered as organ donors. For instance, in 2006, 56% of Europeans were willing to donate an organ after death, but only 12% held an organ donation card (Eurobarometer, 2007). In the U.S., 90% of respondents supported organ donation, but only 50% signed up as organ donors (Department of Health and Human Services, Health Resources and Services Administration, 2019).

Most of the population not recording their willingness to donate suggests that an existing potential donor pool remains unused, especially in opt-in countries. For this reason, this paper examines the effect of a shift from an opt-in to an opt-out system on the magnitude of organ donation rates. In doing so, I exploit the peculiarity of the introduction of opt-out in Argentina in 2005 and Wales in 2015 and use countries that stayed with opt-in to construct ideal counterfactuals for the latter countries. My results show that organ donation rates increased markedly in those countries that introduced opt-out and that the effect persists.

While focusing on the institutional setting for organ donation, my analysis also accounts for further factors identified by previous research as affecting organ donation rates, e.g., socio-demographic characteristics such as age, level of education and religious affiliation[2], as well as medical infrastructure (e.g., Boulware et al., 2002; Gimbel et al., 2003; Mocan and Tekin, 2007; Rithalia et al., 2009). By now, the crucial matter is to transform existing positive public attitudes towards organ donation into actual behavior. Why this is sometimes lacking, in that the individual donation decision is not being made or recorded, and how this relates to legal defaults has been studied in the literature.

First, transaction costs are associated with the decision to donate. These may refer to the amount of time required to obtain and sign an organ donation card or to enroll in an appropriate registry (Abadie and Gay, 2006). Making a choice and registering as a donor or non-donor is often refrained to avoid dealing with one's death. Following the default requires no effort, whereas a change involves physical, cognitive, and emotional costs, especially concerning organ donation decisions (Johnson and Goldstein, 2003). Because of this, transaction costs of donation decisions are higher in opt-in systems than in opt-out systems, despite low registration costs (Abadie and Gay, 2006). Therefore, failure to make and record donation decisions would result in lower effective consent rates in opt-in countries than in opt-out countries.[3]

[2]Religious objections are often cited as a reason for refusing to consent to organ donation, although clergy of various religions endorses organ donation (Oliver et al., 2011; Gallagher, 2016).

[3]For more straightforward comparability, I refer to the effective consent rate as the share of people who opted in in opt-in countries or those who did not opt out in opt-out countries (see, e.g., Johnson and Goldstein (2003)).

Second, in most countries, people can easily evade their own decision by transferring it to the next of kin in case of emergency. However, if they have not discussed organ donation preferences within the family, family members have imperfect information on the deceased's will. Thus, not having made a decision is tantamount to signaling weak (strong) preferences in opt-in (opt-out) countries (Abadie and Gay, 2006). Consequently, effective consent rates of family members for non-registered potential donors would be lower in soft opt-in systems than in soft opt-out systems (Abadie and Gay, 2006).[4]

Third, the two systems differ essentially in their default, 'not donating' (in opt-in countries) or 'donating' (in opt-out countries). Applying the prospect and nudge theory to organ donation policies suggests that maintaining the status quo is the overly favored option (status quo bias) (Samuelson and Zeckhauser, 1988), as is the option where no active decision is required (default effect) (Thaler and Sunstein, 2009). Whereas the default effect can be related to behavioral inertia and perceived norms (Davidai et al., 2012), defaults can also affect decisions by making decision-makers perceive the respective default as implicitly recommended by politicians (Johnson and Goldstein, 2004). This is further reinforced by the fact that people often make decisions in the way they think others do (Thaler and Sunstein, 2009). Furthermore, the particular wording of the question about willingness to donate can impact the choice of family members (framing). So, physicians do not directly ask relatives to consent to organ donation in soft opt-out countries, unlike in soft opt-in countries. Instead, they ask whether there is a reason to believe the deceased would have rejected organ donation. Hence, this suggests that the legislative default itself influences the donation decision of individuals and relatives (Abadie and Gay, 2006). Organ removal is more likely to be rejected under opt-in than under opt-out laws. Thus, organ donation rates are expected to be lower in opt-in countries than in opt-out countries.

Figure 1 shows organ donations per million population (pmp) by organ donation legislation. It suggests a tendency for opt-out countries (light grey) to have higher organ donation rates than those countries in which opt-in applies (dark grey). Figure 1a displays the development of unweighted average organ donation rates in opt-in and opt-out countries. On average, organ donation rates in opt-out countries have steadily been higher than in opt-in countries. This is not driven by a single country (see, e.g., Figure 1b). In addition, average organ donation rates have dropped substantially since the outbreak of the Covid-19 pandemic, which is likely due to the initial uncertainty in transplanting organs from deceased people infected with coronavirus and, secondly, due to the enormous increase in the burden on the healthcare system, especially on personnel in intensive care units. Despite the avail-

[4] Analogously, I refer to relatives' consent in soft opt-in countries or the absence of relatives' refusal in soft opt-out countries as effective consent of family members.

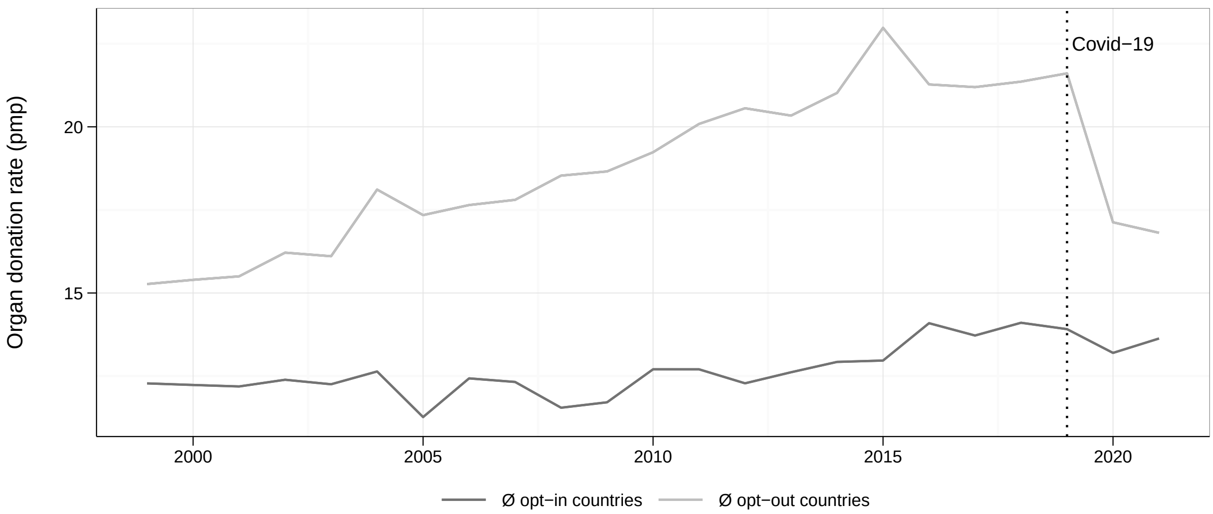
ability of more recent data, the observation period of my study runs until 2019, ruling out any biasing effects of the Covid-19 pandemic. The starting point for my analysis is 1999 since data for several countries are only available from that time onwards.

As shown in Figure 1b, all countries with the highest organ donation rates except one had opt-out in place in 2019, including Argentina and Wales (framed in black). In contrast, most countries with relatively low organ donation rates are among those with opt-in. In this light, controversy about adopting opt-out legislation does not cease in opt-in countries. In Germany, there was a political debate on opt-out in January 2020, but members of the parliament rejected the implementation (Deutscher Bundestag, 2020; Hallam and Prange, 2020). Also, Australia, Canada, Denmark, Romania, Israel, and the U.S. have discussed enacting opt-out (Hyde et al., 2021; Tennankore et al., 2021; Jensen and Larsen, 2020; Grigoras et al., 2010; Scott and Jacobson, 2007; Gundle, 2005). Most recently, a referendum on this issue was held in Switzerland, with most of the population in favor of introducing opt-out legislation (Bundeskanzlei, 2022).

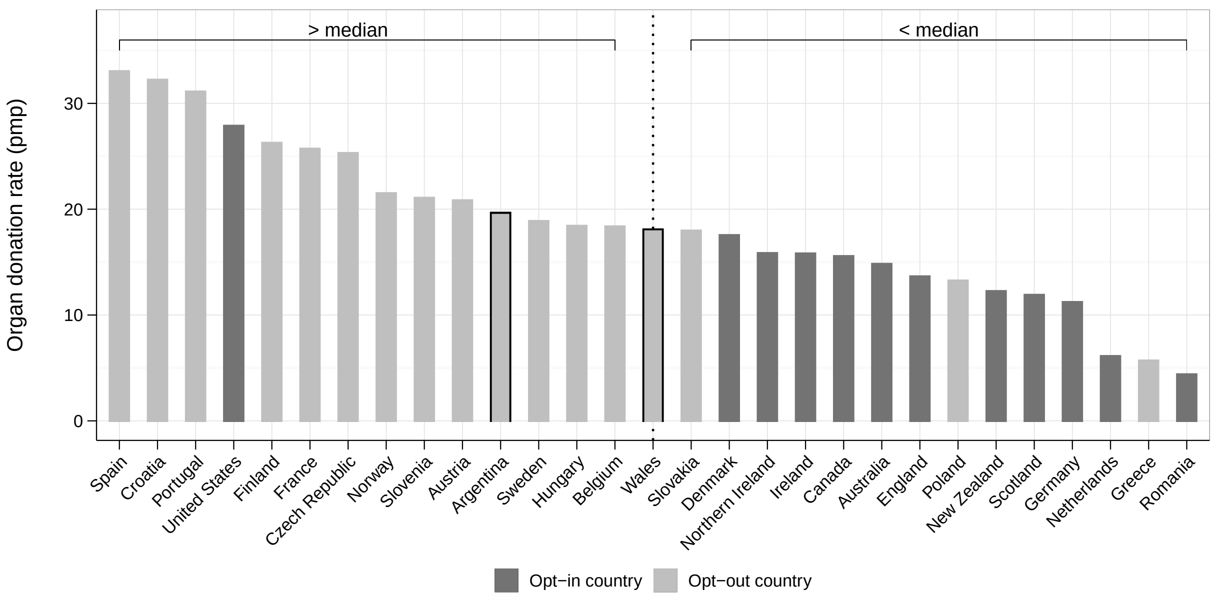
These considerations are based on previous empirical evidence. By using regression analyses, several studies find a positive correlation between opt-out legislation and increased organ donation rates, although the size of the measured effects varies (e.g., Gimbel et al., 2003; Abadie and Gay, 2006; Bilgel, 2012; Shepherd et al., 2014; Ugur, 2015). However, some studies do not find significant effects (e.g., Healy, 2005; Arshad et al., 2019). I contribute to this literature by systematically examining whether the adoption of opt-out is as effective as the former studies suggest. To accomplish this, in contrast to previous studies conducting regression analyses, I apply a counterfactual approach investigating a causal effect of opt-out legislation on organ donation rates. Studies using online experiments, in turn, indicate a positive effect of opt-out laws on individual donation behavior as measured by self-reported hypothetical registration rates (e.g., van Dalen and Henkens, 2014; Moseley and Stoker, 2015). Pointing in this direction, under opt-out, almost twice as many participants could become potential organ donors as under opt-in (Johnson and Goldstein, 2003, 2004; Li et al., 2013). By investigating two real-world settings, I add observational evidence to the findings of this experimental literature on the mechanism that opt-out might increase organ donation rates. Other authors also note that further research is required to examine how societies respond to changes in consent legislation (e.g., Abadie and Gay, 2006). It is precisely this shift in consent models this paper focuses on. In this regard, this study extends the existing literature using pre-post time series designs, as suggested by Shepherd et al. (2014). Finally, I am the first to estimate causal inference between opt-out legislation and organ donation rates using synthetic control method.

Figure 1: Organ donation rates in opt-in and opt-out countries

(a) Average organ donation rates 1999-2021



(b) Organ donation rates by country in 2019



Notes: The upper Figure (a) shows the development of unweighted average organ donation rates between 1999 and 2021 in opt-in (dark grey line) and opt-out (light grey line) countries. The lower Figure (b) reports organ donation rates by country, classified as opt-in (dark grey bar) or opt-out (light grey bar) country, in 2019. Argentina and Wales are framed in black as they changed from opt-in to opt-out within the observation period.

2 Empirical Strategy

2.1 Identification

Several countries have already undertaken a law change from opt-in to opt-out, as the Netherlands did in July 2020 (Government of the Netherlands, 2023). While opt-out came into force in Wales as early as December 2015, opt-in initially remained in place in the other parts of the U.K. (National Health Service (NHS), 2023). It is since May 2020 that opt-out has also applied in England, followed by Scotland in March 2021 and Northern Ireland in Spring 2023. Argentina shifted from opt-in towards opt-out in December 2005 (Mizraji et al., 2007), as Chile did in January 2010 (Zúñiga-Fajuri, 2015) and Uruguay in September 2013 (Uruguay Natural Marca Pais, 2013). Also Iceland transitioned to an opt-out system in 2019 (Iceland Review, 2018).

As depicted in Figure A.1, I initially identified 37 countries for which positive donor numbers were available during the entire observation period. This excludes, for example, Iceland, where data are only available from 2004 onwards.[5] Due to inconsistent regulations within the country, Switzerland, Italy, and Uruguay could not be uniquely assigned and were therefore discarded from the study. Only with the introduction of a national transplantation law in July 2007 opt-in become valid nationwide in Switzerland. Previously, in 17 cantons, opt-out applied, whereas in 5 cantons, opt-in applied (Bundesamt für Gesundheit, 2013). Italy is a particular case, as there is a gradual transformation from opt-in to opt-out in combination with a mandated-choice system (Christen et al., 2018). The type of consent legislation that applies depends on whether the local health authorities had notified the deceased during lifetime to express his or her organ donation preferences.[6] In 2003, opt-out was enacted in Uruguay, but with one restriction. A deceased person who had not refused organ donation was considered an organ donor only if a forensic medical examination was needed, which has no longer been required since 2013 (Alvarez et al., 2009; Uruguay Natural Marca Pais, 2013). Chile and Israel are excluded from the study since these countries have implemented a priority rule that gives patients on the waiting list priority for organ allocation if they or, in the Israeli case, also close relatives are registered donors (e.g., Stoler et al., 2016; Berzon, 2018). Although Chile switched from opt-in towards opt-out during the observation period, an isolated opt-out effect could not be analyzed in the Chilean case as this second

[5]Few countries were discarded, having comparable countries with similar characteristics. This applies to Iran, Cuba, and Turkey due to restricting the pool of potential control units to democratic countries scoring a Democracy Index of more than 6.0 in 2019 (Economist Intelligence Unit, 2020).

[6]If he or she has not recorded a decision despite being requested to do so, opt-out applies to that person; if he or she has not received a request, opt-in applies. But until 2013, the law required general opt-in since there was no possibility of verifying that such a request had been made.

reform, which is likely to have a decisive impact on willingness to donate, accompanied its introduction of opt-out.

In light of the small number of organ donors, the Argentinean government passed a new organ donation law in 2005, implementing a soft opt-out system (Ley 26.066, 2005). Accordingly, the removal of organs was allowed from any capable person over 18 who has not explicitly expressed objection to removing his or her organs after death. While the introduction of the opt-out system in Argentina was accompanied by that of a registry, I argue that any increase in organ donation rates is unlikely to be driven solely by the latter. Rather, there is evidence that a registry can be seen as necessary for an opt-out system to be effective, as opt-out countries have higher organ donation rates only if they involve close relatives and provide a registry where people can document their consent or objection (Bilgel, 2012). Countries that operate such a registry but rely on an opt-in system do not show higher but tend to have lower organ donation rates (Bilgel, 2012). This is also reinforced by the fact that the Welsh population already had the opportunity to register their preferences regarding organ donation prior to the introduction of opt-out.

In response to calls from various stakeholders and aware of surrounding public support, the Welsh government introduced a soft opt-out system through the Human Transplantation (Wales) Act 2013, intending to increase consent rates for organ donation (Palmer and Jones, 2012; Noyes et al., 2019). The new law came into force on December 1, 2015. The British Medical Association (BMA), several patient groups, and the media had pushed for a change from an opt-in to an opt-out system in the U.K. (Noyes et al., 2019).

Finally, the sample covers 27 countries with constant organ donation laws between 1999 and 2019, including 15 with opt-out and 12 with opt-in. The Netherlands, England, Northern Ireland, and Scotland changed from opt-in to opt-out only after 2019 and are therefore considered part of the pool of countries identified as opt-in countries. Argentina and Wales were identified as two cases where organ donation legislation was changed from opt-in to opt-out once during the observed time frame.

2.2 Method

I employ the synthetic control approach introduced by Abadie and Gardeazabal (2003), Abadie et al. (2010, 2015), and Abadie and Cattaneo (2018) to examine the impact of introducing opt-out legislation on organ donation rates. The synthetic control method allows estimations of effects in settings where a single event occurs at an aggregate level and accounts for unobserved time-varying factors. The underlying idea is to create a counterfactual based on a weighted combination of all untreated units (pool of potential control units) that closely match the trend of the pre-treatment outcome and related characteristics. Combining untreated units may allow a better comparison with the treated unit than a single untreated unit. Thus, the matching algorithm generates a synthetic control unit depicting how the treated unit would have developed without the treatment.

For this purpose, the weights w_j that sum up to one are determined by minimizing the Root Mean Squared Prediction Error (RMSPE) over the time intervals before the intervention t $(t < T_0)$. The RMSPE measures the difference in the outcome variable of a treated unit Y_{1t} and that of its counterfactual:

$$\text{minimize } RMSPE = \left[\sum_{t=1}^{T_0}\left[\frac{\left(Y_{1t} - \sum_{j=2}^{J+1}(w_j * Y_{jt})\right)^2}{T_0}\right]\right]^{1/2}, \tag{1}$$

with $J+1$ observed units in periods $t = 1, ..., T$, whereby unit $j = 1$ is the only unit exposed to the intervention in $t = T_0$. The synthetic control estimator of the treatment effect in a post-intervention period t $(t \geq T_0)$ is defined as follows:

$$\hat{a}_{1t} = Y_{1t} - \sum_{j=2}^{J+1}(w_j * Y_{jt}). \tag{2}$$

The results of the synthetic control method provide causal inferences if certain assumptions are fulfilled. First, the trajectories of the outcome variable of the treated unit and the synthetic counterfactual sufficiently resemble one another in the period before the intervention; second, the pool of potential control units only includes those with similar characteristics to the treated unit; third, there are no spillover effects on untreated units; and fourth, no other reforms are implemented. The synthetic control method then also controls indirectly for unobserved, time-varying confounders, assuming that only units have similar trajectories in the outcome variable, which are also similar in the observed and unobserved determinants of the outcome variable.

As outlined in Section 3, generated synthetic counterparts for Argentina and Wales each show similar trends in organ donation rates before adopting opt-out. In addition, all countries, treated and untreated, have in common that next of kin are involved in the decision-making process. All these countries are also comparable concerning fundamental civil liberties guaranteed. Moreover, spillover effects are negligible in this study setting: First, countries that stick to opt-in are not affected by countries switching towards opt-out, as, in general, the organ donation law of the country in question is applied depending on the place of death.[7] Second, since policymakers and societies worldwide have considered adopting opt-out, public debates are not limited to those countries that have enforced the law change. I solely consider countries that have not changed their organ donation legislation as the pool of potential control units. I also exclude countries from the sample that have implemented any other reform regarding willingness to donate organs, such as introducing the priority rule.

I construct a synthetic counterpart separately, each for Argentina and Wales, by aligning the organ donation rates from the pool of potential control units in the period before the intervention, in the case of Argentina to Argentinean rates in 1999-2005 and in the case of Wales to Welsh rates in 1999-2015. I do so that in the different pre-intervention periods, Argentina and Wales do not differ markedly from their synthetic counterparts in terms of either organ donation rates or other predictors. According to the short observation period only short-term effects could be addressed based on this sample.

In the first step, I estimate the effect on organ donation rates to measure an opt-out policy's effectiveness. In the second step, I run placebo tests based on ranked post/pre-Mean Squared Prediction Error (MSPE) ratios for each placebo, checking the validity of the results. As introducing opt-out was decided years earlier than was implemented, it seems reasonable to consider anticipation effects possible if assuming the decision to change the law surrounded by a public debate encourages people to make and document the decision to become an organ donor. Thus, I capture such by running a further specification, using an alternative treatment year before opt-out came into force for the placebo in time that leaves a sufficiently long period before the treatment.

2.3 Data

I use annual data on organ donation rates at the country level from 1999 to 2019. Actual deceased organ donor numbers are compiled predominantly from the Global Observatory on Donation and Transplantation (GODT, 2023). Where possible, missing values are supplemented with data from the International Registry in Organ Donation and Transplantation (IRODaT, 2023).[8] Data on organ donors within the U.K. come from NHS Blood and Transplant Annual Activity Reports (NHS Blood and Transplant, 2023).[9] The data include all deceased persons from whom at least one organ was removed for the purpose of transplan-

[7] Although there are organ transfers between countries, this does not affect the rate of organs donated, i.e., removed, in the respective countries, but only the number of those who receive an organ.

[8] Numbers for the year 1999 for Canada are taken from Bardell et al. (2003) and for Portugal from Matesanz (2001).

[9] As the U.K. data are reported per fiscal year from April 1 to March 31 of the following year, I assign the data to the year that is covered for the most part.

tation. The fact that the possibility of multi-organ donation is limited in quantity and depends on medical factors allows looking at the number of donors rather than the number of organs donated. Only organ donation after death is addressed because the possibilities for living donation are restricted for medical reasons and are subject to numerous further legal requirements. To ensure comparability of the data, I only account for organ donations after brain death, as organ donation after cardiac death is not permitted in all countries of interest. Respective organ donation rates are computed using data on population size.

By screening multiple data sources, I determine countries' organ donation policies based on the statutory entrenchment (see Table A.1). Ultimately, the organ donation regulations of all the countries examined in the study are classified as soft, as relatives are invariably involved in the decision for organ donation of the deceased, at least to some extent. Additionally, several predictors are included, enhancing the comparability of the treated unit and its counterfactual (for a detailed description of the data, see Appendix B). The number of deaths caused by cerebrovascular diseases (CVD) and road traffic accidents (RTA) per 100 000 population is contained, as these are the most common causes of death among potential organ donors. In line with previous research, data on the gross domestic product (GDP) per capita, health expenditures as a share of GDP, and hospital beds per 1 000 people are taken into account as proxies for a country's health care system quality and infrastructure. I also incorporate the school enrollment in tertiary education as an education proxy, the proportion of Catholics out of total population as a religion proxy, and the population share of people ages 65 and above as further socio-demographic characteristics the literature identified as being related to the willingness to donate organs. Finally, data on the presence or absence of organ donor registries at the regional or national level is included. In donor registries, individual organ donation decisions are centrally captured and thus easily accessible by medical personnel. I only use one outcome lag to ensure that all covariates remain relevant in constructing the synthetic control unit (Kaul et al., 2022). Except for the latter, all predictors are averaged over the pre-intervention period.[10]

[10]The data set has no missing values in the outcome variable. It is only in the predictor variables that linear interpolation estimates replace missing data. Otherwise, there would not be sufficient data on the predictor variable of education for single countries within the pool of potential control units in the Argentinean pre-intervention period until 2005.

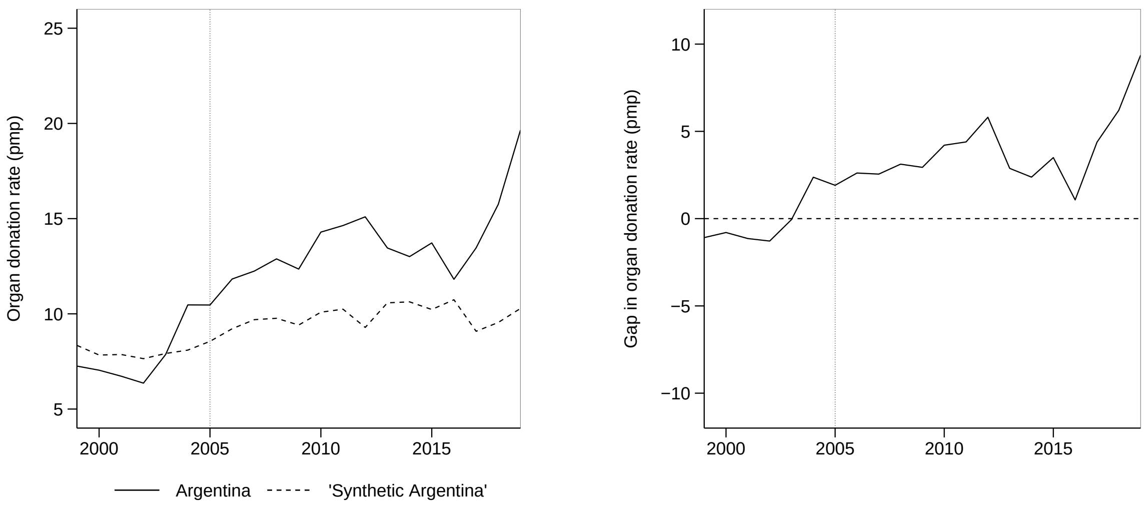
3 Results

3.1 Argentina

A 'Synthetic Argentina' composed of 54.1% Scotland, 26.7% Germany, 15.5% Northern Ireland, and 3.7% Ireland best matches the Argentinean trend in organ donation rates before introducing opt-out (for country weights, see Table C.1 column (1)). All other countries in the pool of potential control units are weighted at zero. As reported in the upper panel of Table C.2, Argentina and 'Synthetic Argentina' had, on average, similar organ donation rates of around eight organ donors pmp between 1999 and 2005, with an unweighted sample mean (without Argentina) of around 12 organ donors pmp (for organ donation predictor means and weights, see Table C.3), suggesting 'Synthetic Argentina' provides a better comparison for Argentina than the average of the whole sample.

Figure 2: Organ donation rates in Argentina and 'Synthetic Argentina'

(a) Path (b) Gap



Notes: The left Figure (a) shows the organ donation rate in Argentina (solid black line) and in 'Synthetic Argentina' (dashed black line) derived from the synthetic control method. The right Figure (b) plots the gap between the two functions. The vertical black dotted line reflects the introduction of an opt-out policy in Argentina in 2005.

Figure 2 shows the trajectories of organ donation rates in Argentina compared to its counterfactual. 'Synthetic Argentina' (dashed black line) does not precisely reflect the Argentinean trend in organ donation rates (solid black line) until 2005, but it does so reasonably well. The pre-treatment fit index Adhikari and Alm (2016) developed is 0.173, indicating a sufficiently good fit.[11] However, the observed pre-intervention period is relatively short because organ donation has not been widely performed for a long time. Until 2002, Argentina has about one organ donor pmp less than 'Synthetic Argentina'. After similar organ donation rates in 2003, the organ donation rate in Argentina is steadily higher than in its predicted counterfactual.

In the 14 years after the intervention, the average organ donation rate with 13.87 organ donors pmp is estimated to be substantially higher in Argentina than in its counterfactual with 9.91 organ donors pmp (+40%) (see upper panel of Table C.2). In 2019, Argentina reached an organ donation rate of almost 20, doubling the organ donation rate before the introduction of opt-out in 2005. In contrast, the organ donation rate in 'Synthetic Argentina' remained relatively unchanged in the post-intervention period. Thus, synthetic control method results indicate a distinctly positive effect of implementing an opt-out policy. With Argentina having around 9 organ donors pmp more than 'Synthetic Argentina', at a rough estimate, additional 1 260 patients with organ failure received an organ in 2019 alone, assuming three transplanted organs per donor on average. However, 760 people on the Argentinean waiting list died in the same year (Domínguez-Gil, 2020).

Argentina's organ donation rate was already rising a few years before the change in the law and, in particular, had seen a sharp increase after 2016. The latter is likely to be related to a case that has attracted much attention in Argentina, where a 12-year-old girl in need of a heart transplant initiated a campaign to raise awareness for organ donation but did not receive a life-saving organ (European Connected Health Alliance Group, 2022). After she died in 2017, Argentina further reinforced its opt-out system with the 'Justina Law' named after her, weakening the veto rights of next of kin but strengthening the donor's decision. Regardless of the manner of consent, the donor's wishes should be honored, while an override by next of kin requires convincing evidence of the donor's changed preferences (Zúñiga-Fajuri and Molina-Cayuqueo, 2018). The increase in organ donation rates coinciding with this strengthening of the opt-out system endorses my findings.

3.2 Wales

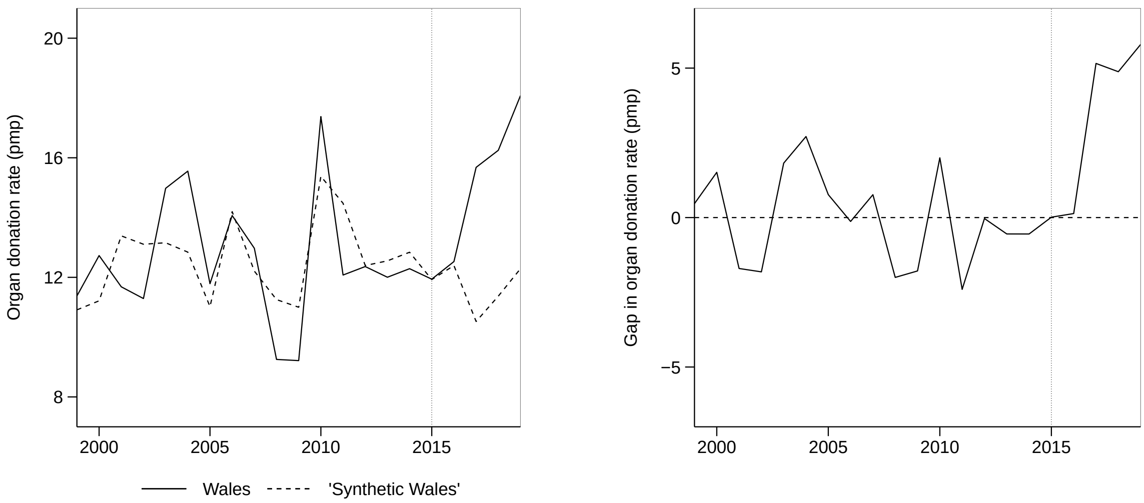
A 'Synthetic Wales' representing the Welsh trend in organ donation rates and other predictors prior to its law change consists of 39.3% Germany, 36.1% Romania, 13.6% U.S., 10.8% Scotland, 0.2% England, and 0.1% New Zealand (for country weights, see Table C.1 column (2)). All remaining countries in the pool of potential control units obtain zero

[11] The fit index would be zero in a perfect fit, whereas a value equal to or greater than one would indicate a poor fit. Although Adhikari and Alm (2016) refer to the pre-treatment fit as good with an index of no more than 0.1, my model is at least reasonably close.

weights. As indicated in the lower panel of Table C.2, between 1999 and 2015, Wales and 'Synthetic Wales' faced similar average organ donation rates of about 13 organ donors pmp, with an unweighted sample mean (without Wales) of about 12 organ donors pmp (for organ donation predictor means and weights, see Table C.4).

Figure 3: Organ donation rates in Wales and 'Synthetic Wales'

(a) Path (b) Gap



Notes: The left Figure (a) displays the organ donation rate in Wales (solid black line) and in 'Synthetic Wales' (dashed black line) inferred from the synthetic control approach. The right Figure (b) plots the gap between both functions. The vertical black dotted line shows the implementation of an opt-out legislation in Wales in 2015.

From the time perspective, Wales and its equivalent have comparable organ donation rates until 2015 (Figure 3a). However, the trajectories of organ donation rates in Wales (solid black line) and 'Synthetic Wales' (dashed black line) do not fit perfectly, but fairly good in the pre-intervention period. The pre-treatment fit index by Adhikari and Alm (2016) is 0.118, indicating favorable goodness of fit. One difficulty in matching the trend lies in the enormous volatility of the variable of interest. As also visualized in Figure 3b, Wales and its counterfactual already differ in some years before the intervention. However, the differences after the intervention point steadily in the same direction and are larger. In the four years following the intervention, the organ donation rate in Wales averaged 15.63 organ donors pmp, considerably higher than in 'Synthetic Wales' with estimated 11.64 organ donors pmp (+34%) (see lower panel of Table C.2). In 2019, Wales had 18 organ donors pmp, one and a half times as many as in 2015, right before the legislation was changed. In comparison, the organ donation rate in 'Synthetic Wales' has barely changed over the same period, even initially dropping after 2015. Hence, in the case of Wales, my findings also suggest a positive effect of the law change. Visual evidence also indicates that the opt-out effect is unfolding one year after its introduction, as the organ donation rate only rises considerably after 2016. As Wales had nearly six organ donors pmp more than its synthetic counterfactual in 2019, roughly estimated around 60 additional lives could be saved, again assuming, on average, three transplanted organs per donor. Nevertheless, even with the opt-out system implemented, not all patients who need an organ have received one.

4 Robustness

4.1 Placebo Tests

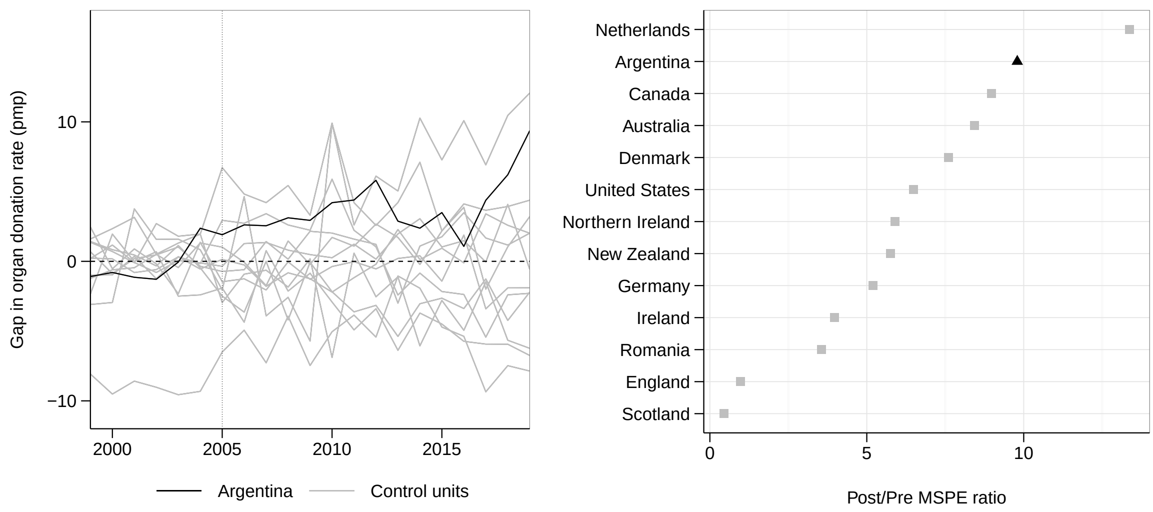
Two issues commonly occur with synthetic controls. First, taking into account several covariates comes at the expense of finding a good pre-treatment fit in the outcome variable. I address, at the aggregate level, any factors available identified in the literature to affect organ donation rates. In favor of my analysis, most covariates receive positive weights in at least one specification, barely considering the lagged outcome variable (Table C.3, Table C.4). Second, a small number of countries in the pool of potential control units forms the synthetic counterfactual. This is not an issue in my analysis as both 'Synthetic Argentina' and 'Synthetic Wales' are a weighted combination of multiple countries rather than being constructed from a single country. Furthermore, the countries that comprise the synthetic counterpart should have similar characteristics to the treated unit. 'Synthetic Argentina' only consists of European countries, but there are no geographically close countries from South America in the pool of potential control units. In general, most countries in the pool of potential control units are OECD member states, only Argentina and Romania are under negotiation. Having all countries in the sample with an adequate legal and ethical framework on organ donation also supports the selection of the pool of potential control units. The synthetic control algorithm incorporates other parts of the U.K. in constructing a 'Synthetic Wales'. Even though these countries are closely related, I argue spillover effects are unlikely in the context of organ donations. The potential organ donor must have lived in Wales for at least one year before death and also died in Wales for the organ donation law to apply (Noyes et al., 2019). Although a public information campaign accompanied the introduction of the opt-out system in Wales, the effect is unlikely to be due to this alone, as other countries in the pool of potential control units also conducted campaigns without a similar increase in organ donation rates.

I submit the results to several robustness checks evaluating their validity further: First, I conduct placebo tests in space, addressing the statistical significance of the treatment effect. In doing so, I assign the treatment to countries unaffected by the intervention. By applying the synthetic control method analogously to these countries, I estimate placebo effects. I can then compare the effect of introducing opt-out in Argentina and Wales with the estimated placebo effects. The opt-out effect is significant if the estimated effect for the treated unit is exceptionally high compared to the placebo effects. Figure 4 and Figure 5 show the results of the placebo tests for all units in the pool of potential control units (light grey) and the ranked post/pre-MSPE ratios obtained.[12]

Figure 4: Robustness tests in the case of Argentina

(a) Placebo test

(b) Post/Pre-MSPE ranking



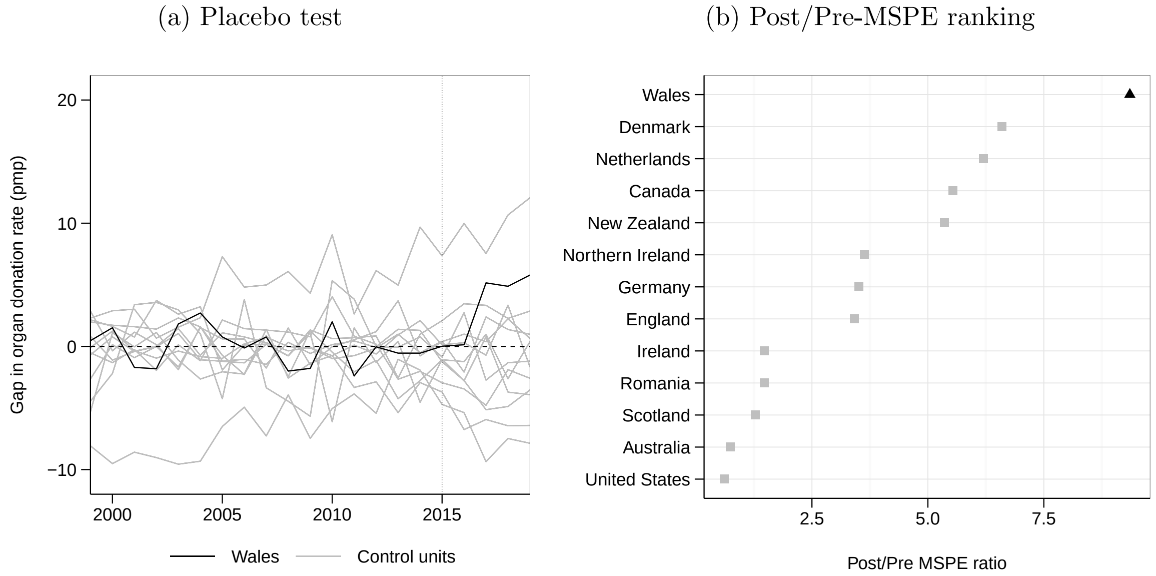
Notes: The left Figure (a) illustrates the gap in organ donation rates between each country and its synthetic counterpart, with Argentina represented by the black line and the 12 countries in the pool of potential control units by light grey lines. The right Figure (b) shows the ranked post/pre-MSPE ratios for Argentina and all countries in the pool of potential control units.

As visualized in Figure 4a, Argentina is among those countries that have seen an increase in organ donation rates since 2005. After the intervention, the difference in organ donation rates between Argentina and 'Synthetic Argentina' is about ten times larger than before the intervention (Figure 4b). In favor of my findings, Argentina has the second highest post/pre-MSPE ratio among 13 countries in the pool of potential control units.

As shown in Figure 5a, the true treatment effect in Wales is larger than most placebo treatment effects. In addition, Wales has the highest post/pre-MSPE ratio of all countries

[12] As a large gap between a country's organ donation rate and that of its synthetic counterfactual does not equal a large treatment effect if the synthetic control does not closely reflect the pre-intervention organ donation rate, the post-intervention MSPE is divided by the pre-intervention MSPE.

Figure 5: Robustness tests in the case of Wales



Notes: The left Figure (a) displays the gap in organ donation rates between each country and its counterfactual, with Wales visualized by the black line and the 12 countries in the pool of potential control units by light grey lines. The right Figure (b) reports the ranked post/pre-MSPE ratios for Wales and all countries in the pool of potential control units.

in the pool of potential control units (Figure 5b), which also strongly supports my results. The gap in organ donation rates between Wales and its synthetic counterfactual is about nine times larger following the intervention than before.

In a second step, I conduct a placebo study in time reassigning the treatment year prior to the actual intervention. I each choose the year about halfway through the pre-treatment period. However, it is only limitedly suitable for Argentina since there is no adequately long pre-treatment period.

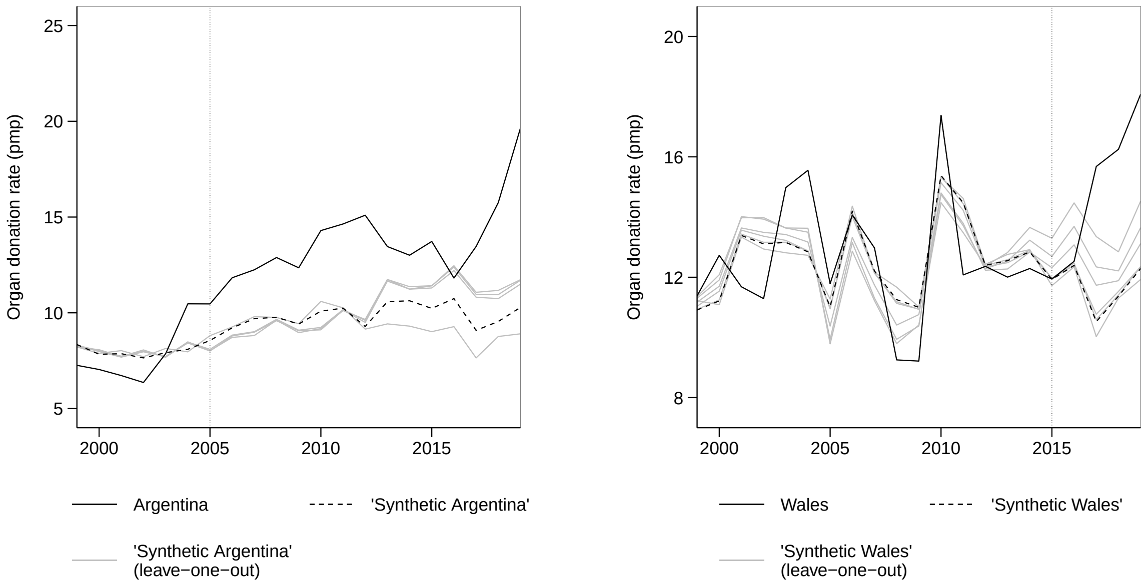
The robustness check for Argentina, defining 2003 as the treatment year, shows that the pre-treatment trend in organ donation rates in Argentina and its counterfactual fit more precisely than in the baseline model. Divergence in organ donation rates being around 5 000 times larger after 2003 than before (see Figure D.1) suggests that the effect of introducing the opt-out legislation in Argentina started with the public and political debate. The robustness check for Wales indicates Wales and 'Synthetic Wales' do not match well in organ donation rates trends before the backdated treatment year to 2007, nor is there a univocal effect afterwards (see Figure D.2), affirming my analysis.

4.2 Leave-one-out

As a further robustness test, I examine whether certain countries in the pool of potential control units drive the results. By exposing these countries to a leave-one-out procedure, I check the sensitivity to changes in country weights. I run separate estimations repeating the basic model but omitting one of the countries from the pool of potential control units with a positive weight in each iteration.

Figure 6: Leave-one-out procedure

(a) Argentina (b) Wales



Notes: Figures (a) and (b) illustrate synthetic control results from the leave-one-out procedure for Argentina and Wales. The solid black line represents the organ donation rate in Argentina and Wales, respectively, and the dashed black line in their synthetic counterparts of the baseline model. Grey lines show synthetic control method results, each excluding one country from the pool of potential control units.

The solid grey lines in Figure 6 denote that the resulting synthetic counterparts to Argentina and Wales slightly differ from those in the baseline scenario (dashed black line). In the case of Argentina (Figure 6a), the results are robust to excluding single countries from the pool of potential control units. When discarding Germany, Northern Ireland, or Scotland, the organ donation rate in 'Synthetic Argentina' increases slightly more sharply from 2011 onward. However, there is still an effect that is somewhat smaller. Without Ireland being part of the pool of potential control units, the effect is even more visible than in the baseline model. In the case of Wales, the results also hold when eliminating individual countries from the pool of potential control units (Figure 6b). Excluding Germany, New

Zealand, the U.S., Romania, Scotland, or England only leads to some lost goodness of fit in the pre-treatment period but shows similar results as in the baseline scenario.

By the leave-one-out procedure, I also rule out possible bias arising from the Netherlands, England, Northern Ireland, and Scotland having switched from opt-in to opt-out after 2019. In the above separate specifications, these countries are not part of the pool of potential control units if they have not already received zero weights.

5 Conclusion

I conduct a comprehensive quantitative ex-post analysis using the synthetic control method to investigate the impact of switching from opt-in to opt-out on organ donation rates. The estimates for implementing an opt-out policy in Argentina and Wales show similar patterns. In both cases, the trend for the treated unit outperforms the predicted synthetic control after the law has changed. I find that adopting an opt-out system raised organ donation rates in Argentina by 40%. In Wales, the introduction of opt-out led to a 34% increase in organ donation rates. The effect already occurred in Argentina two years before implementation and in Wales with a one-year delay, while there is no evidence of the effect being temporary. My findings suggest that countries switching from opt-in to opt-out gain substantial positive impacts on organ donation rates. Thus, given an opt-out policy's relatively low monetary costs, the benefits of changing the law seem high. Still, transitioning from an opt-in to an opt-out system is likely successful if accompanied by an information campaign to raise awareness and if a register is kept to record one's decision on organ donation.

The placebo studies imply that the results are not simply due to a lack of predictive power and do measure the opt-out effect. Also conducting sensitivity analyses supports the credibility of the results. My findings are transferable to other countries with similar characteristics that are considering implementing opt-out legislation. However, due to limited data, long-term effects still need to be measured, which future research may shed more light on. The mechanisms behind the opt-out effect, such as certainty for medical staff in pushing organ donation, higher consent rates by relatives for organ donation, or whether it is those of the potential donors themselves require further empirical investigation. While sizeable, the impact of opt-out does not suffice to solve the organ shortage problem completely but may mitigate it.

Thus, there is a need for ongoing research in the field of organ donation, both to identify additional measures to increase organ donation rates further and to more thoroughly evaluate the effectiveness of organ donation systems. The development of future organ donation rates in Iceland, the Netherlands, England, Northern Ireland, Scotland, and Switzerland should be carefully monitored after changing their organ donation system. It remains to be seen whether expectations of increasing organ donation rates resulting from the switch to an opt-out system will be fulfilled. The results of the organ donation legislation changes in these countries will indicate whether my findings can be generalized and externally validated.

Appendices

A Sample selection

Figure A.1: Sample selection

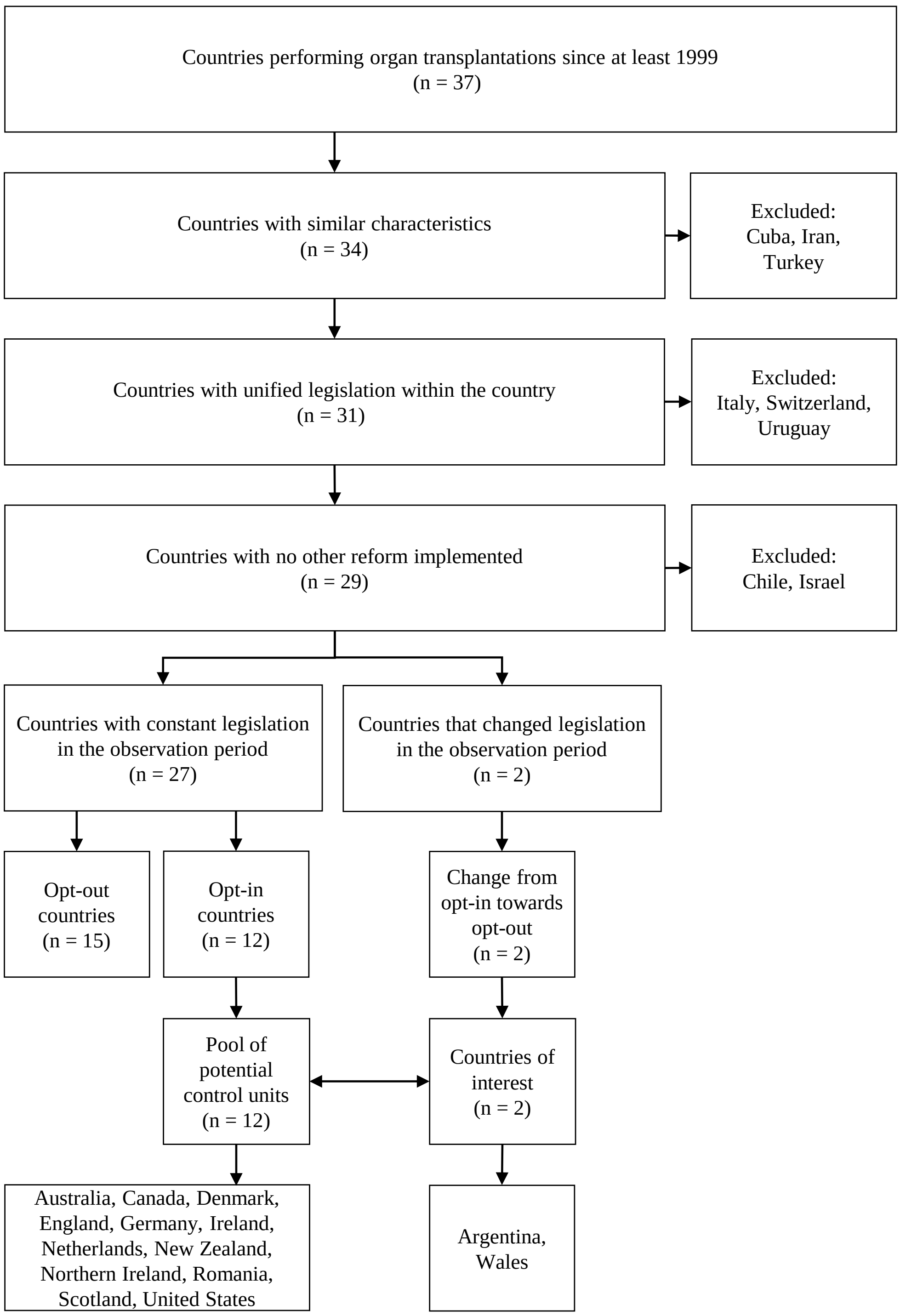


Table A.1: Organ donation legislation

Country	Consent legislation	Source
Australia	(soft) opt-in	[1], [6], [7], [10]
Canada	(soft) opt-in	[1], [6], [7], [10]
Denmark	(soft) opt-in	[1], [4], [6], [7], [10]
England	(soft) opt-in[a]	[9]
Germany	(soft) opt-in	[1], [4], [6], [7], [10]
Ireland	(soft) opt-in	[1], [4], [6], [7], [10]
Netherlands	(soft) opt-in[a]	[1], [4], [5], [6], [7], [10]
New Zealand	(soft) opt-in	[1], [7], [10]
Northern Ireland	(soft) opt-in[a]	[9]
Romania	(soft) opt-in	[1], [4], [10]
Scotland	(soft) opt-in[a]	[9]
United States	(soft) opt-in	[1], [6], [7], [10]
Argentina	changed from (soft) opt-in to (soft) opt-out in 2005	[8]
Wales	changed from (soft) opt-in to (soft) opt-out in 2015	[9]
Austria	(soft) opt-out	[1], [4], [6], [7], [10]
Belgium	(soft) opt-out	[1], [4], [6], [7], [10]
Croatia	(soft) opt-out[b]	[1], [3], [7], [10]
Czech Republic	(soft) opt-out	[1], [4], [6], [7], [10]
Finland	(soft) opt-out	[1], [4], [6], [7], [10]
France	(soft) opt-out	[1], [4], [6], [7], [10]
Greece	(soft) opt-out	[1], [2] , [4], [6], [7]
Hungary	(soft) opt-out	[1], [3], [4], [6], [7]
Norway	(soft) opt-out	[1], [4], [6], [7], [10]
Poland	(soft) opt-out	[1], [4], [6], [7], [10]
Portugal	(soft) opt-out	[1], [4], [6], [7]
Slovakia	(soft) opt-out	[1], [4], [6], [7]
Slovenia	(soft) opt-out[c]	[1], [3], [4], [6], [10]
Spain	(soft) opt-out	[1], [6], [7], [10]
Sweden	(soft) opt-out	[1], [4], [6], [7], [10]

Notes: The table shows countries that kept their organ donation legislation unchanged during the observation period 1999-2019, with [1] Abadie and Gay (2006), [2] Canellopoulou-Bottis (2000), [3] European Federation for Organ Donation (EFOD) (2023), [4] Gimbel et al. (2003), [5] Government of the Netherlands (2023), [6] Healy (2005), [7] Horvat et al. (2010), [8] Mizraji et al. (2007), [9] National Health Service (NHS) (2023), [10] Rosenblum et al. (2012a).

[a] changed to opt-out later than 2019.

[b] Authors in [4] categorize Croatia's consent legislation as opt-in.

[c] Authors in [7] categorize Slovenia's consent legislation since 2000 as opt-in.

B Data description and sources

Population: Population data are from the World Bank WDI database except for U.K. (World Bank, 2022b). Data for England, Northern Ireland, Scotland, and Wales are from Office for National Statistics, U.K. (2022b).

GDP: Gross domestic product per capita is in current U.S. dollars. Data are mainly from the World Bank WDI database (World Bank, 2023b). Data for England, Northern Ireland, Scotland, and Wales are from Office for National Statistics, U.K. (2022b) and calculated in U.S. dollars using historical exchange rates.

Health expenditures: Current health expenditures are in % of GDP. Data are predominantly from the World Bank WDI database (World Bank, 2023a). Absolute data for England, Northern Ireland, Scotland, and Wales are obtained from Public Expenditure Statistical Analyses (PESA) of the U.K. government (GOV.UK, 2022).

Hospital beds: Hospital beds are per 1 000 population and cover inpatient beds in hospitals of any category, at most including both acute and chronic care beds. Data are mainly from the World Bank WDI database (World Bank, 2023c). Absolute numbers for England are extracted from The King's Fund (2023), for Northern Ireland from the Department of Health, Social Services and Public Safety (2022), for Scotland from Public Health Scotland (2019), and for Wales from StatsWales (2021), Welsh government.

Death from CVD and RTA: Deaths from cerebrovascular diseases and road traffic accidents are per 100 000 people. All data are retrieved from the Global Health Data Exchange (GHDx) Database, using the Global Burden of Disease (GBD) results tool by the Institute for Health Metrics and Evaluation (IHME) (GHDx, 2023).

Population 65+: Population ages 65 and above is given as a percentage of the total population. Other than for U.K., data are from the World Bank WDI database (World Bank, 2022a). Data for England, Northern Ireland, Scotland, and Wales are from Office for National Statistics, U.K. (2022a).

Tertiary education: Tertiary enrollment is the gross enrollment ratio, measured as the total number of students in tertiary education, irrespective of age, divided by those of the age officially corresponding to the tertiary level. Except for U.K., education data are from the World Bank WDI database (World Bank, 2022c). Total numbers on students in higher education for England, Northern Ireland, Scotland, and Wales are from Higher Education Statistics Agency (2021) and population data of the relevant age groups for calculating the gross enrollment ratio are from Office for National Statistics, U.K. (2022a).

Religion: The share of Catholics is reported as a percentage of the total population. Data until 2013 come from TheGlobalEconomy.com (2023) and data for single following years are retrieved from Cahoon (2023). Data on religious affiliation in England, Northern Ireland, Scotland, and Wales are based on catholic church statistics, census and household survey data (Leyshon, 2012; Faith Survey, 2023; Northern Ireland Statistics and Research Agency, 2023; Scottish Government, 2019; National Records of Scotland, 2023; Cheney, 2023).

Donor registry: Donor registry is a dummy variable taking the value of 1 in the presence of a donor registry (zero otherwise). The notion of 'donor registry' relates to registries where consents and/or objections can be captured. Information is taken from Rosenblum et al. (2012b).

C Descriptive Statistics and estimation results

Table C.1: Synthetic control country weights

	Argentina	Wales
	(1)	(2)
Australia	0	0
Canada	0	0
Denmark	0	0
Germany	0.267	0.393
Ireland	0.037	0
Netherlands	0	0
New Zealand	0	0.001
Romania	0	0.361
United Kingdom		
England	0	0.002
Northern Ireland	0.155	0
Scotland	0.541	0.108
United States	0	0.136

Notes: The table shows the country weights assigned by the synthetic control method for 'Synthetic Argentina' and 'Synthetic Wales'.

Table C.2: Synthetic control estimates

	Argentina	'Synthetic Argentina'	Full sample (without Argentina)	Ratio Argentina / 'Synthetic Argentina'
before the legislation change (1999-2005)				
organ donation rate	8.03	8.04	12.42	100 %
after the legislation change (2006-2019)				
organ donation rate	13.87	9.91	12.86	140 %
	Wales	**'Synthetic Wales'**	**Full sample (without Wales)**	**Ratio Wales / 'Synthetic Wales'**
before the legislation change (1999-2015)				
organ donation rate	12.53	12.58	12.42	100 %
after the legislation change (2016-2019)				
organ donation rate	15.63	11.64	13.96	134 %

Notes: The table shows average organ donation rates for Argentina and Wales and their counterfactuals, each before and after the legislation change.

Table C.3: Organ donation predictor means and weights Argentina

	Argentina	'Synthetic Argentina'	Full sample (without Argentina)	Weights
predictors (1999-2005)				
GDP per capita	5404.04	16 309.60	28 159.62	0.045
Health expenditures	7.71	7.68	7.99	0.413
Hospital beds	4.06	7.01	5.01	0.000
Deaths				
from CVD	69.94	179.17	96.92	0.000
from RTA	14.58	13.42	10.21	0.389
Population share of 65+	9.86	14.52	13.81	0.000
Tertiary education	59.88	48.32	69.03	0.061
Religion				
Catholic population	90.23	19.21	28.32	0.000
Donor registry	0.00	0.70	0.82	0.092
Organ donation rate 2001	6.72	7.86	12.69	0.000

Notes: The table shows organ donation predictor means before the organ donation legislation change in Argentina. GDP per capita is in current U.S.$, health expenditures are in % of GDP, hospital beds are per 1 000 people, deaths from CVD and RTA are per 100 000 people, population ages 65 and above is in % of total population, tertiary education is enrollment ratio in % of the population in the corresponding age group, catholic population is in % of total population. Donor registry is a dummy variable taking the value of 1 in the presence of a donor registry (zero otherwise).

Table C.4: Organ donation predictor means and weights Wales

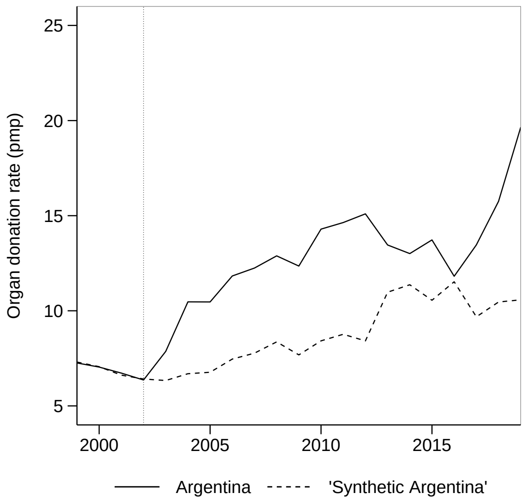
	Wales	'Synthetic Wales'	Full sample (without Wales)	Weights
predictors (1999-2015)				
GDP per capita	29 210.33	30 806.11	37 418.08	0.178
Health expenditures	9.01	8.88	8.84	0.533
Hospital beds	4.35	6.19	4.41	0.001
Deaths				
from CVD	104.00	98.21	88.63	0.036
from RTA	5.91	8.07	8.55	0.029
Population share of 65+	18.13	15.99	14.69	0.000
Tertiary education	62.44	62.39	71.73	0.199
Religion				
Catholic population	5.84	30.20	27.95	0.009
Donor registry	1.00	0.61	0.83	0.006
Organ donation rate 2001	11.68	13.39	12.69	0.001

Notes: The table shows organ donation predictor means before the organ donation legislation change in Wales. GDP per capita is in current U.S.$, health expenditures are in % of GDP, hospital beds are per 1 000 people, deaths from CVD and RTA are per 100 000 people, population ages 65 and above is in % of total population, tertiary education is enrollment ratio in % of the population in the corresponding age group, catholic population is in % of total population. Donor registry is a dummy variable taking the value of 1 in the presence of a donor registry (zero otherwise).

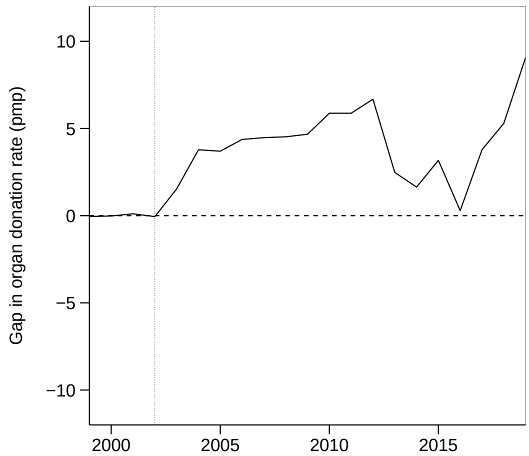
D Placebo results for alternative treatment years

Figure D.1: Placebo in time and space results for Argentina

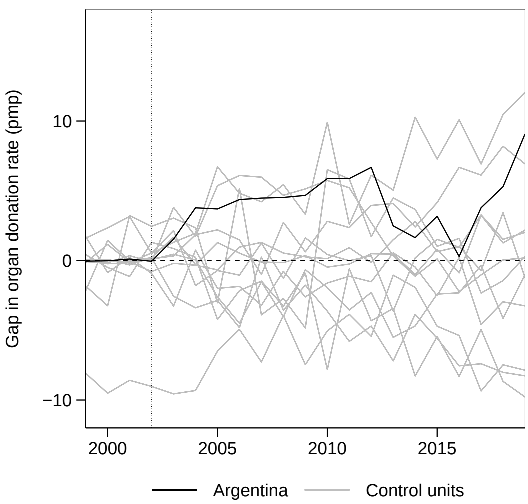
(a) Path 2002



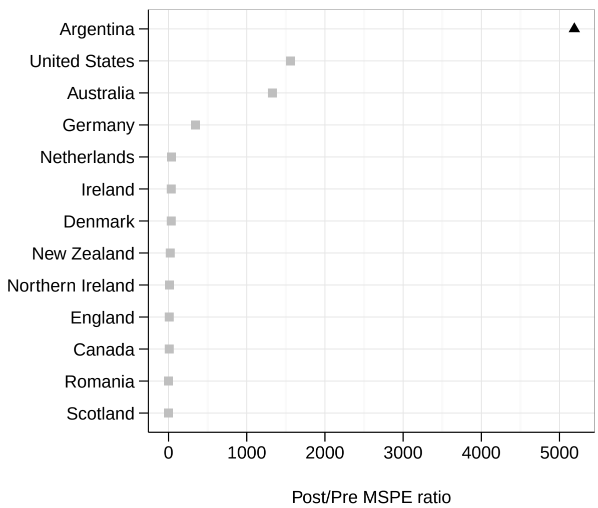
(b) Gap 2002



(c) Placebo test 2002



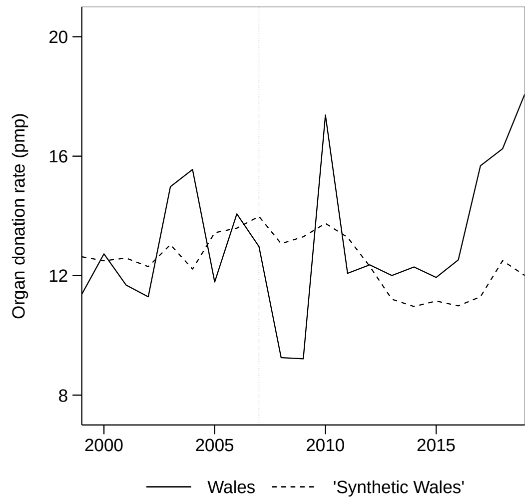
(d) Post/Pre-MSPE ranking 2002



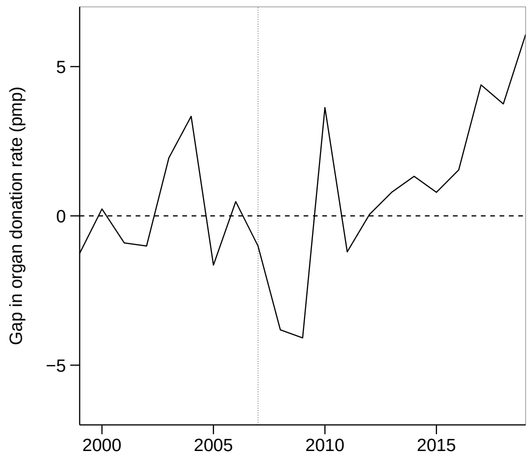
Notes: The upper left Figure (a) illustrates the organ donation rate in Argentina (solid black line) and in 'Synthetic Argentina' (dashed black line) derived from the placebo in time study. The upper right Figure (b) plots the gap between both functions. The vertical black dotted line represents the alternative treatment year 2002. The lower left Figure (c) illustrates the gap in organ donation rates between each country and its synthetic counterpart, with Argentina represented by the black line and the 12 countries in the pool of potential control units by light grey lines. The lower right Figure (d) shows the ranked post/pre-MSPE ratios for Argentina and all countries in the pool of potential control units.

Figure D.2: Placebo in time and space results for Wales

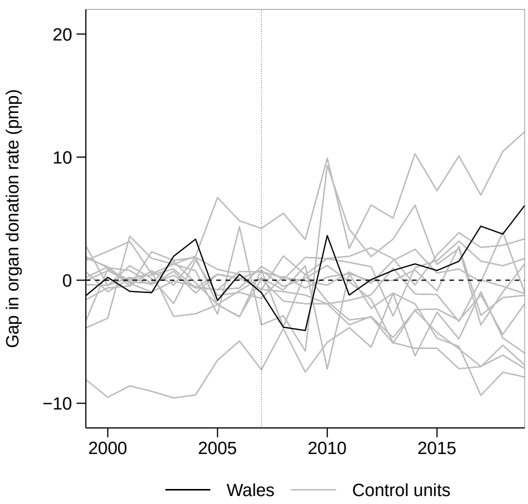
(a) Path 2007



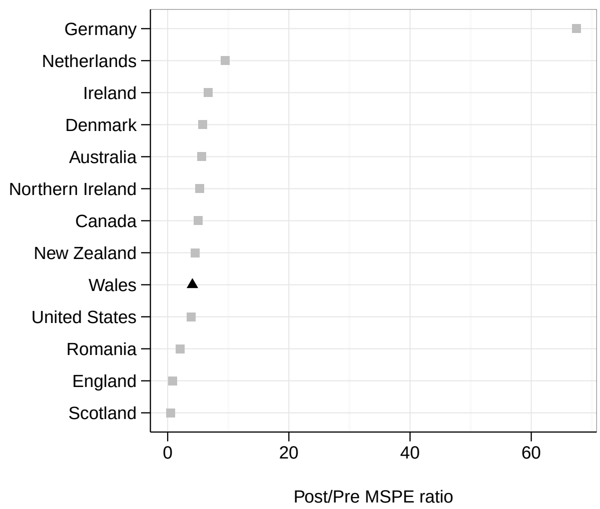
(b) Gap 2007



(c) Placebo test 2007



(d) Post/Pre-MSPE ranking 2007



Notes: The upper left Figure (a) displays the organ donation rate in Wales (solid black line) and in 'Synthetic Wales' (dashed black line) inferred from the placebo in time study. The upper right Figure (b) plots the gap between both functions. The vertical black dotted line shows the alternative treatment year 2007. The lower left Figure (c) displays the gap in organ donation rates between each country and its counterfactual, with Wales visualized by the black line and the 12 countries in the pool of potential control units by light grey lines. The lower right Figure (d) reports the ranked post/pre-MSPE ratios for Wales and all countries in the pool of potential control units.

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