Public Health 236 (2024) 436–440

Contents lists available at ScienceDirect

Public Health

journal homepage: www.elsevier.com/locate/puhe

Original Research

Opt-out defaults do not increase organ donation rates

M. Dallacker [a], L. Appelius [a], A.M. Brandmaier [b, c, d], A.S. Morais [a], R. Hertwig [a, *]

[a] Center for Adaptive Rationality, Max Planck Institute for Human Development, Lentzeallee 94, 14195 Berlin, Germany
[b] Center for Lifespan Psychology, Max Planck Institute for Human Development, Lentzeallee 94, 14195 Berlin, Germany
[c] Department of Psychology, MSB Medical School Berlin, Rüdesheimer Str. 50, 14197 Berlin, Germany
[d] Max Planck UCL Centre for Computational Psychiatry and Ageing Research, Lentzeallee 94, 14195 Berlin, Germany

ARTICLE INFO

Article history:
Received 27 March 2024
Received in revised form
26 July 2024
Accepted 10 August 2024

Keywords:
Organ donation
Defaults
Explicit consent
Presumed consent
Longitudinal analysis
Health policy

ABSTRACT

Objectives: To increase organ donation rates, many countries have switched from an opt-in ('explicit consent') default for organ donation to an opt-out ('presumed consent') default. This study sought to determine the extent to which this change in default has led to an increase in the number of deceased individuals who become organ donors.
Study design: Longitudinal retrospective analysis.
Methods: We conducted a retrospective analysis of within-country longitudinal data to assess the effect of changing the organ donation default policy from opt-in to opt-out. Our analysis focused on the longitudinal deceased donor rates in five countries (Argentina, Chile, Sweden, Uruguay, Wales) that had adopted this change. Using a Bayesian aggregated binomial regression model, we estimated the odds of organ donation within each country over time, as well as the effect of the policy switch.
Results: Switching from an opt-in to an opt-out default did not result in an increase in donation rates when averaged across countries. Moreover, the opt-out default did not lead to even a gradual increase in donations: there was no discernible difference in the linear rate of change of donations after the change in default. Finally, the COVID-19 pandemic was associated with a reduction in the odds of donation across all five countries.
Conclusions: Our longitudinal analysis suggests that changing to an opt-out default does not increase organ donation rates. Unless flanked by investments in healthcare, public awareness campaigns, and efforts to address the concerns of the deceased's relatives, a shift to an opt-out default is unlikely to increase organ donations.

Introduction

Organ shortage is a pressing global health problem. In the United States alone, nearly 20 people die every day while waiting for a transplant.[1] Worldwide, the situation has been exacerbated by a drop in transplant activity during the COVID-19 pandemic.[2] One policy solution thought to be particularly promising for increasing the number of organs available for transplantation from deceased donors (known as 'deceased organ donation') is changing the default from opt-in to opt-out. In an opt-out ('presumed consent') system, all adults are automatically considered organ donors after their death unless they explicitly withdraw their consent during their lifetime; in an opt-in ('explicit consent') system, an individual must provide explicit consent for donation during their lifetime for their organs to be donated after their death. Countries employ various approaches to record citizens' organ donation preferences, including online registries, living wills, and donor cards.

In 2003, a groundbreaking study analysed the organ donation consent rates of 11 European countries as a function of their default policy[3] and found an enormous disparity between the two defaults: In the seven opt-out countries, the presumed consent rate (i.e., the proportion of the population that did not opt out) was, on average, 98%; in the four opt-in countries, the consent rate (i.e., the proportion that opted in) was only about 15%. This gap in consent rates has sometimes been attributed to inertia—the argument being that most people stick with the default donor status because doing so requires no effort. Aiming to harness this effect on consent rates, countries including England, Scotland, and the Netherlands have recently switched to an opt-out default; countries such as Germany, Canada, and the United States are considering following suit.

* Corresponding author. Tel.: +49 30 82406 202.
E-mail address: hertwig@mpib-berlin.mpg.de (R. Hertwig).

https://doi.org/10.1016/j.puhe.2024.08.009

But does an opt-out default truly achieve the ultimate goal of increasing actual organ donation rates? Numerous other factors may hinder organ donation, including an absence of necessary and effective infrastructure (e.g., national transplant coordination network and adequately trained medical personnel), religious beliefs, a lack of public awareness about organ donation, and family objections.[4–7] In nations where informed consent is a cornerstone of healthcare and families have rights over the deceased's remains, obtaining permission from next of kin remains necessary even in an opt-out organ donation system.[7] Merely transitioning to an opt-out system may not automatically eliminate barriers to donation. It is therefore imperative to assess the system's effectiveness in improving actual donation rates.

Since the initial analysis,[3] reliable data on default policies and how they affect organ donation rates have become more readily available. A systematic review comparing donation rates across countries found that estimates of the size of the effect of an opt-out default varied.[8] The review's authors concluded that presumed consent alone is unlikely to explain the variation in organ donation rates between countries and that factors such as mortality from road traffic accidents or availability of transplant centres may also play a part. Another study controlling for such country-specific factors found that an opt-out policy might lead to a rise in deceased organ donations, but also to a decrease in living (e.g., kidney) donations.[9] Finally, a recent analysis of all member countries of the Organisation for Economic Co-operation and Development controlling for country-specific socio-economic factors found no significant difference in total deceased donation rates between opt-in and opt-out countries, but significantly fewer living donors in opt-out countries.[10]

Together, these findings suggest that an opt-out policy default does not necessarily mean higher organ donation rates. In fact, it is difficult to pinpoint the causal effects of opt-out defaults: The cross-sectional studies comparing donation rates between countries with opt-in and opt-out defaults are observational, making it challenging to draw definitive causal inferences about how the default policy influences organ donation rates. Complicating things further, these countries vary substantially on factors likely to affect donation rates, such as culture, religion, health infrastructure (e.g., availability of trained surgeons and transplant centres), and education. Although most studies controlled for some such factors, a risk of residual confounding remains.

One principled approach to address the limitations of cross-sectional studies is to analyse the change in deceased organ donations within each country over time. Longitudinal studies have more power than cross-sectional studies in detecting causal relationships because they observe the temporal order of events within a country and exclude the influence of country-specific differences on donation rates. A few longitudinal studies have investigated the effect of switching from opt-in to opt-out on donation rates (see Steffel et al.[11] for a review), but the results are difficult to interpret as they did not control for secular trends (i.e., changes in donation rates over time caused by other factors, including improvements to the national transplant coordination network and to transplantation procedures[9]). To overcome these problems, we analysed longitudinal within-country deceased organ donation rates in countries that have switched from an opt-in to an opt-out default policy, controlling for secular trends and country-specific factors.

Methods

Study design and data sources

We began by retrieving the list of all countries with data available on the International Registry in Organ Donation and Transplantation (IRODaT; www.irodat.org), a free and open database, and screened the Global Observatory on Donation and Transplantation database (GODT; www.transplant-observatory.org) for additional data. Due to the lack of data on living donation, our analysis focused on organ donations from deceased donors.

We classified countries into explicit consent (opt-in) or presumed consent (opt-out) and identified transition dates based on existing literature, websites of health ministries and governments, legislative texts, and email correspondence with contact people at organ donation organisations and health ministries. Countries were categorised into explicit consent or presumed consent based on the World Health Organization's (WHO) definitions:[12] A country was classified as having an explicit consent default if cells, tissues, or organs may be removed for transplantation only if a deceased person 'expressly consented to such removal during [their] lifetime', orally or in writing (depending on domestic law), or as having a presumed consent default if cells, tissues, or organs may be removed 'unless the person had expressed [their] opposition before death by filing an objection with an identified office, or an informed party reports that the deceased definitely voiced an objection to donation'.

Next, we focused on countries classified as having a presumed consent default. We further restricted our analyses to countries that changed from explicit to presumed consent no later than December 2019, thus ensuring a minimum of three annual observations after the switch and making it possible to discern a trend. This cut-off date led to the exclusion of countries that have only recently switched from explicit to presumed consent, such as England and the Netherlands. Countries classified as having an explicit consent default were also excluded. By applying these selection criteria, we obtained a set of 39 presumed consent countries (see Table S1).

For two reasons, only five of the 39 presumed consent countries could ultimately be included in our analysis. The first reason was the scarcity of historical data for countries that implemented the policy change prior to the launch of the IRODaT database in 1996. Generally speaking, reliable data only became available from this point onwards. For instance, Italy changed its default in 1967, but the first Italian data recorded in the IRODaT database stem from 1993. It is worth noting that of the 39 countries in Table S1, 24 changed their default before 1995—there is thus a substantial historical data gap. The second reason for excluding countries was that the presumption of consent was a common practice before official legislation was introduced; the change in legislation therefore did not reflect an actual change in practice. In total, 27 of 39 countries were excluded due to insufficient data alone, four countries were excluded due to the unofficial practice of presumed consent alone, and three countries were excluded for both reasons (see Table S1 for details). This resulted in a final set of five countries that were included in the analysis: Argentina, Chile, Sweden, Uruguay, and Wales.

The number of actual deceased donors for these five countries was obtained from the IRODaT database and, when possible, supplemented with information from transplantation organisations. An actual deceased donor is an individual in whom an operative incision was made with the intent of organ recovery for transplantation, or from whom at least one organ was recovered for transplantation. In the case of Chile, gaps in the data were filled with information from the Global Observatory on Donation and Transplantation. Swedish data prior to 1993 and for 2022 were provided by Scandiatransplant (www.scandiatransplant.org). Data for Wales were retrieved from the NHS Organ and Tissue Donation and Transplantation activity reports.[13] We obtained numbers of actual deceased donors for all five countries until 2022. The study onset, however, differs between countries: data for Sweden start in 1988, for Chile in 1993, for Argentina in 1995, for Uruguay in 1998, and for Wales in 2000.

Population data were retrieved from the UN World Population Prospect,[14] data on overall deaths (i.e., deaths due to all causes) from the WHO Mortality Database,[15] data on road traffic deaths from the Global Health Observatory,[16] data on stroke-related deaths from the Global Burden of Disease Study,[17] and gross domestic product (GDP) per capita from the World Development Indicators of the World Bank.[18] Data for Wales stem from the Office for National Statistics (United Kingdom)[19] and the Welsh government's data repository.[20]

Bayesian modelling

Regression models were specified and fitted in Stan[21] using the R package rstanarm.[22] We used the default weakly informative scaled Gaussian priors with an unscaled variance of 2.5 on intercept and regression coefficients to make extreme estimates less plausible and provide stability of parameter estimation. Credibility intervals, pseudo adjusted R^2, and Bayes factors were computed with the R package bayestestR.[23] Models were estimated using Monte Carlo Markov chains with a default sampler with 50,000 iterations and 1000 warm-up steps. We report median values of the posterior density and their 95% credibility intervals transformed such that they represent proportional change in the odds of donation. Bayes factors were computed with the Savage–Dickey density ratio approximation. We report logarithmic Bayes factors against a point null model that excludes a given predictor. We interpret Bayes factors larger than $\log(3) = 1.1$ as weak evidence and those larger than $\log(10) = 2.3$ as strong evidence. Positive logarithmic Bayes factors indicate evidence for a predictor; negative Bayes factors indicate evidence against inclusion of a predictor.

We complemented our primary analysis with a sensitivity analysis that systematically varied the width of the weakly informative priors. The analysis was written in R and is fully reproducible using the repro approach.[24,25] All data and analysis scripts are available at: https://osf.io/wgxyv/?view_only=1b2a6a01e0cc47a38cca5103c0789dea.

Longitudinal analysis

Our longitudinal analysis was based on aggregated binomial regression models with a logarithmic link function. The outcome variable was the odds of deceased organ donation. Differences across countries were effect-coded. Predictors included the global average of deceased donors at study onset, country-specific deviations from that onset, global annual change, country-specific deviations from the global change, a dummy-coded variable indicating whether an opt-out policy was in place at a given point in time, and a dummy-coded variable for the duration of the COVID-19 pandemic, including the years 2020, 2021, and 2022, the last year in our dataset. This classification is consistent with the WHO's timeline, which first referred to COVID-19 as a pandemic in March 2020 and lifted its classification as a public health emergency of international concern in May 2023. Table S2 shows the posterior median estimates for the regression coefficients and their credibility intervals. Table S3 shows the Bayes factors gauging the evidence for or against inclusion of each predictor. A sensitivity analysis revealed that altering the prior width (to between half and twice the default width) did not change the interpretation of the relevant Bayes factors.

We further investigated whether GDP per capita, stroke-related mortality rates, and mortality rates from road traffic accidents predicted the odds of organ donation. GDP per capita is a primary indicator of a country's economic health and performance. Strokes and road traffic accidents are often significant sources of organ donations, particularly in the case of brain-dead donors, as the organs from these donors are usually healthy and suitable for transplantation. We added both predictors to our model and fitted the model again (see Tables S4 and S5 for posterior parameter estimates and corresponding Bayes factors).

As a robustness check, we tested two variants of the initial model without predictors. One model variant predicted the odds of donation when using the number of deceased persons per year rather than the total population as base rate (Tables S6 and S7). The second variant used the same base rate for predicting donation odds as the initial model (i.e., using the total population), but incorporated a difference in slopes before and after the default change (Tables S8 and S9). This involved introducing an interaction term between policy and time, allowing us to assess whether the rate of change in donations varied after the switch in default. The slopes in the model after the policy change can indicate whether the opt-out default requires time to effectively increase organ donations, potentially showing a gradual acceleration (or deceleration) in donation rates over time. By conducting these robustness checks, we aimed to ensure that we had thoroughly investigated any potential effects of the change in default from opt-in to opt-out on deceased organ donation rates.

Results

The model without covariates fitted the data adequately (McFadden's adjusted $R^2 = 0.63$). Observed donor rates with superimposed model predictions are shown in Fig. 1. The model predicted an average annual increase in the odds of organ donation of 2.69% (CI: 2.29%–3.1%), regardless of the change in default policy. There was strong evidence (logBF = 18.37) that the COVID-19 pandemic was associated with a 19.74% decrease in the odds of donation (CI: 15.99%–23.34%), but donation rates appear to be slowly recovering after the severe decline in 2020 (Fig. 1). Importantly, we found strong evidence against the inclusion of policy change as a predictor (logBF = −5.07). The change in policy was even associated with a small decrease of 1.67% in the odds of donation (CI: −3.51% to 6.58%).

We further investigated whether GDP per capita, stroke-related mortality rate, and the mortality rate from road traffic accidents covaried with the odds of donation by including these covariates as predictors in the model (see Tables S4 and S5). There was no evidence for the inclusion of GDP (logBF = −0.51). Although there was strong evidence against the inclusion of road traffic deaths as a predictor (logBF = −2.87), there was very strong evidence supporting the inclusion of stroke-related mortality (logBF = 16.80). Contrary to intuition, a one-unit increase in stroke-related mortality rate was associated with a 2.7% decrease in the odds of organ donation (CI: 2.1%–3.4%). This finding may, however, reflect a suppression effect: Since lower stroke-related mortality rates are associated with later time points and later time points with higher donation rates, this may lead to an apparent association between lower stroke-related mortality rates and higher donation rates. Finally, the model with covariates yielded strong evidence against including policy change as a predictor (logBF = −4.69); the posterior median effect was an undesirable policy-related decrease of 2.62% (CI: −4.68% to 9.32%) in the odds of organ donation.

The robustness checks applied to our initial model yielded results similar to our original analyses. Note that the robustness checks did not include any covariates. First, we used the number of overall deaths per year rather than the total population as base rate (see Tables S6 and S7). Again, there was strong evidence against the inclusion of policy change as a predictor (logBF = −4.79); the median effect was a decrease of 2.52% in the odds of donation (CI: −2.61% to 7.41%). Second, we added an interaction between time and policy change to the model, using the total population as a

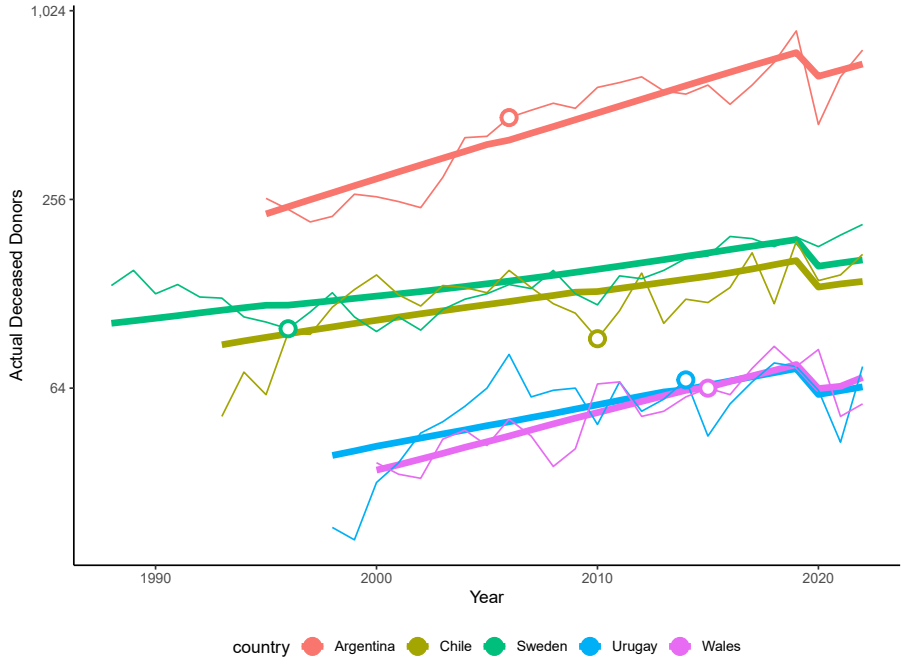

Fig. 1. Absolute number of actual deceased organ donors per year. The y-axis is in logarithmic units. Circles represent the time point of policy change, thin lines represent the observed data, and thick lines represent model predictions.

base rate as we had done initially (see Tables S8 and S9). We found strong evidence against including the interaction term (logBF = −3.73) and against including the policy change alone (logBF = −3.94). The similarly large Bayes factors indicate clear evidence favouring the simpler model without the interaction term, as there was no difference in slopes after the policy change. The posterior median effect of policy change alone showed a 5.63% decrease in the odds of donation (CI: −4.19% to 14.52%).

Discussion

Results from five longitudinal within-country analyses suggest that a policy change from an opt-in (explicit consent) to an opt-out (presumed consent) default does not increase organ donation rates from deceased donors. The results of the various statistical analyses converge on the conclusion that switching from an opt-in to an opt-out default, if anything, results in a slight decrease in donation rates when averaged across countries. Moreover, our results indicated that the opt-out default did not lead to even a gradual increase in organ donations: There was no discernible difference in the linear rate of change of donations after implementing the new default. The results also showed a reduction in deceased donations with the onset of the COVID-19 pandemic, with only a slow recovery observed up to 2022.

Our longitudinal approach to analysing within-country data over time overcomes the limitations of previous cross-sectional analyses. First, it effectively differentiates the impact of the policy shift from changes that would have occurred anyway due to other factors. Second, it minimises the confounding influence of country-specific factors that impact organ donation rates but are difficult to measure, such as the health system, culture, or religion. A limitation of our analysis is its scope, as only five of the 39 presumed consent countries could be included. This is primarily due to the scarcity of historical data for the many countries that changed to an opt-out policy before official data recording began. The finding that a change in organ donation default from opt-in to opt-out does not clearly boost deceased donations aligns with the results of extant cross-sectional analyses.[9,10]

In general, there seems to be a consensus in the organ donation literature that there is no 'magic bullet' for increasing organ donation rates. Our findings are in line with this perspective. A policy switch from opt-in to opt-out is unlikely to work unless flanked by substantial investments in healthcare infrastructure and training of medical personnel. For instance, Spain, which currently has the highest donation rate worldwide, implemented an opt-out transplant system in 1979, but donation rates did not begin to rise until 10 years later. This development has been attributed to other important changes in the infrastructure, such as the introduction of a transplant coordination network and education programs.[26]

Family objections, often a significant barrier to deceased organ donation, should also be addressed. In many countries—including Chile, Sweden, and Wales—the consent of next of kin is necessary for organ donation. The veto power given to families has also been cited as a reason why the opt-out default does not significantly improve donation rates over the opt-in system.[27,28] Considering expressed preferences, whether of the deceased or their relatives, overrides the default. Ultimately, the implications for transplantation outcomes between opt-in and opt-out defaults only differ in the rare cases when no explicit statements of preference were made by either the deceased or their relatives. A previous cross-country scenario analysis has shown that, when family preferences are honoured, shifting from an opt-in to an opt-out default alone would only increase organ recovery by 0%–5%.[29]

The same analysis also showed that family intervention improves organ retrieval in opt-in systems but hinders it in opt-out systems.[29] A possible explanation comes from psychology, where experimental evidence has demonstrated that, under opt-out systems, relatives tend to perceive an individual's presumed preference to donate as weaker and more ambiguous than a stated preference because the choice to donate is passive.[30] This contrasts with a default opt-in or a mandated choice system (where people are required by law to register their organ donation preferences), in

which the choice to donate is an active one. Given that people may not have explicitly communicated their donation wishes to their families,[31] presumed consent acts as a weaker signal of underlying preference, thus adding uncertainty to a family's deliberations on whether to donate their deceased relative's organs. Facing this uncertainty, families are more likely to refuse consent. Opt-out systems therefore need to implement measures to minimise the ambiguity in the signal attached to presumed consent. For instance, initiatives that encourage individuals to openly express their donation preferences whilst alive may help increase organ donations in opt-out systems. Likewise, a suitable human resource infrastructure is needed in hospitals, with professionals who are trained to have difficult conversations with the relatives of the deceased.

Our results suggest that governments considering an opt-out default should reflect carefully on their decision. Consistent with previous cross-sectional studies, our longitudinal analysis suggests that switching from an opt-in to an opt-out default yields no clear advantage in terms of increasing organ donation rates. Several complementary measures may be necessary to support a new default system, including public education, improvements to healthcare infrastructure, and initiatives to reduce the ambiguity perceived by relatives around the deceased's presumed consent. An alternative worth considering is to move away from a default system altogether and implement a two-option registration system that allows citizens to explicitly register either their consent or their objection to organ donation.[29] This is the case in mandated choice systems that legally require all citizens to register their organ donation preferences, for instance, when they register for a driver's license or renew their identity card. Two-option registration systems address the potential problem of inertia and avoid making an implicit recommendation, thus reducing social pressure to register as a donor,[32] while also requiring an active choice that may help reduce and even eliminate the perceived ambiguity that leads to higher family-refusal rates.

Author statements

Acknowledgments

The authors thank Eric Johnson, Dan Goldstein, and Zoe Rahwan for helpful comments, and Deborah Ain and Susannah Goss for editing the manuscript.

Ethical approval

The project did not require ethical approval as the authors analysed publicly available, non-identifiable data from different countries.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing interests

The authors report no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2024.08.009.

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