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**Article**

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## THE EFFECT OF PRESUMED CONSENT DEFAULTS ON ORGAN DONATION

JESSICA LI AND TILL NIKOLKA<sup>1</sup>

### Opt-in versus opt-out consent systems

Many developed countries face a chronic shortage of human organs for transplantation and are struggling to meet growing demand for organs. From 1995 to 2005, the number of patients placed on waiting lists for organ transplants grew on average at a rate of four percent per year. Growing waiting times jeopardize patients' health; for example, the median waiting time in the US for a kidney transplant is over three years, and median waiting times for hearts and livers are seven months and two years respectively (Howard 2007). The chronic shortage of organs has incited debate over policy design to increase approval for donations among donors, and thus improve the availability of organs for transplantation.

In this context, a widely discussed policy measure concerns the legislative default for cadaveric organ donation. In many countries, health authorities are considering the benefits of an opt-out compared with an opt-in consent system for deceased organ donation. Countries with opt-in systems, such as the US, the UK and Germany, procure organs from deceased donors under the informed consent principle. By law, potential donors must give express consent in order to enter the donor pool, which is often reflected on a donor registration card or a driver's license. On the other hand, an opt-out system reflects a presumed consent policy; deceased individuals, in theory, are automatically classified as potential donors unless they had explicitly "opted out" of donation. Individuals who do not wish to potentially donate after death must actively express their opposition, for example, by filling out a form. Examples of countries with opt-out policies include Austria, France and Norway. As Abadie and Gay (2006) note, the specific content and enforcement of laws vary greatly among countries with opt-out policies. For instance, in Austria presumed consent legislation is applied strictly, and the fact that the deceased individual did not opt out ultimately determines that the individual is registered

as a donor, overriding family approval. However, most countries with opt-out policies like Spain still consider the families' wishes in practice, and families are allowed to veto donation, even if the deceased individual previously revealed a preference for donation. Consent legislation on the national level is often complicated by the fact that laws also vary between state, provincial or local governments. Wales, for example, recently decided to change from opt-in to opt-out consent, while the rest of the UK still maintains an informed consent law.

### Arguments in favor of opt-out consent regulation

In the behavioral economics literature, changing to a presumed consent regime is expected to increase the number of registered donors by influencing attitudes and behavior. First, "opt-out consent systems are likely to bridge the gap between people's intentions and their behavior by removing the need to undertake any actions in order to become an organ donor" (Shepherd, O'Carroll and Ferguson 2014). Results from a US 1993 Gallup survey support the theory that the need for deliberate, physical effort is a barrier between people's preferences and registration: although 85 percent of Americans favor organ donation and 69 percent would like to donate their organs after death, in practice only 28 percent actually become donors in registries (Gallup 1993). Second, individuals take the default as a suggestion by policymakers and are more likely to act according to what they view as the recommendation (Johnson and Goldstein 2003; McKenzie, Liersch and Finkelstein 2006). Finally, according to the concept of loss aversion, people gravitate toward the status quo because the losses weigh more heavily psychologically than the equivalent gains in a change; thus people in opt-out countries are less likely to deviate from the default. In essence, presumed consent laws could increase deceased donation rates because opt-out systems influence people's attitudes, decision-making behavior, and consent decisions in favor of deceased organ donation.

Basic descriptive statistics for a sample of OECD countries suggest that countries with opt-out policies do indeed tend to have more deceased donors per million of the population (pmp) than countries with opt-in policies. Table 1 shows donation and transplantation rates for the OECD countries in 2014, excluding countries with populations smaller than two million.<sup>2</sup> The mean number of actual deceased donors pmp in 2014 was 19.46

<sup>1</sup> Ifo Institute (both).

<sup>2</sup> Table 1 is also available in the DICE Database (DICE Database 2016).

in opt-out countries versus 13.59 in opt-in countries, or approximately six percentage points more. Likewise, the average number of deceased organ transplantations pmp and the average share of deceased organ transplantations out of both living and deceased transplantations were comparatively higher in countries with presumed consent laws. Germany and Austria – which have different consent default systems, but are otherwise very similar with respect to cultural, social and institutional characteristics – provide an interesting comparison. While Germany, an opt-in country, had 10.45 actual deceased donors pmp in 2014, Austria, an opt-out country, had more than double at 24.94 deceased donors pmp. Finland and Denmark can be compared in a similar manner: as an opt-in country Denmark had 14.29 actual deceased donors pmp in comparison to Finland, which had 22.41 deceased donors pmp.

### Causal evidence from empirical analysis?

On the other hand, living donation rates might be higher in informed consent countries, where deceased donation rates tend to be lower: in 2014 there were 16.03 living organ transplantations pmp on average in opt-in countries, versus 8.20 on average in opt-out countries. Abadie and Gay (2006) explain that “it seems likely that an increase in the supply of cadaveric organs would be followed by a reduction in the supply of organs from living donors” because of the substitution effect for applicable organ donations. The patterns revealed in descriptive statistics are consistent with results published in several empirical studies, such as Abadie and Gay (2006); Shepherd, O’Carroll and Ferguson (2014).

Moreover, countries substantially vary in their culture, religion, transplant infrastructure, and educational level – which are likely to influence a country’s propensity toward donation regardless of its consent system, as well as the type of consent system a country adopts in the first place. Beyond legislative defaults, the empirical literature considers other variables that are hypothesized to affect organ donation rates to ensure that these variables do not interfere with results. The most common variables include the road traffic accident mortality rate, GDP, the number of hospital beds per 10,000 people, the percentage of the population that identifies as Catholic, and whether the country is more likely to use civil or common law. GDP is positively associated with deceased organ donation rates because transplantation occurs primarily in wealthy countries and requires expensive infrastructure to support it (Horvat

et al. 2010). Previous research has found that presumed consent countries tend to be predominantly Catholic, while informed consent laws are more likely to occur in countries with a legislative system based on common law like the United States or Britain (Abadie and Gay 2006). Many studies also use the number of hospital beds as a proxy for quality and abundance of healthcare. Finally, countries with higher rates of vehicle accidents may be more likely to have a larger supply of donor organs (Shepherd, O’Carroll and Ferguson 2014). Even after controlling for these covariates, most studies still find higher deceased donation rates in opt-out countries. The 2006 study by Abadie and Gay, which examines donation rates for 22 countries over ten years, finds that presumed consent countries have roughly 25 percent to 30 percent higher donation rates than informed consent countries.

Healy (2006) uses a time series of 16 OECD countries to investigate variation in procurement rates. While he finds similar results as Abadie and Gay (2006), Healy (2006) does not interpret the results as causal. Instead, Healy argues that countries with opt-out regimes also invest more effectively in the organization and logistics of the procurement and transplant systems. For example, in the early 1990s Spain created a network of highly trained transplant coordinator teams and implemented them in donor hospitals. Teams are also responsible for donor detection and recruitment efforts. Spain subsequently saw striking growth in donation rates throughout the 1990s (and in Table 1, Spain remains at the top in terms of number of deceased donors pmp and number of deceased organ transplantations pmp as of 2014). What is notable is that, in practice, Spanish hospitals still ultimately defer to the families’ wishes, suggesting that hospital teams are key to successful recruitment and procurement. Healy concludes that opt-out countries are more likely to pay attention to “more fine-grained organizational differences” – like “better training, clear delegation of responsibility, a strong presence in hospitals” – and that these factors, rather than presumed consent legislation, are responsible for higher rates. Additionally, Healy conjectures that countries that adopt presumed consent laws are probably more favorably disposed toward organ donation before these laws are even established.

Unlike Healy, most researchers find that consent type does play some causal role – however, “as part of a causal change rather than a single causal factor” (Shepherd, O’Carroll and Ferguson 2014). Bilgel (2012) examines the interactions between a presumed consent legal re-

gime and other customs and institutions in 24 countries over a 14-year period. Bilgel elaborates: “The evidence confirms that countries in which presumed consent is enacted produce substantially higher deceased donor rates. However, the magnitude of this impact highly depends on the involvement of the family and the establishment of donor administration systems [...]” The study advocates that hospitals still seek family consent, regardless of the preferences of the deceased individual, while maintaining a registry to document people’s preferences; countries that do not seek family consent could face a public backlash that would encourage many individuals to deliberately register as non-donors. Countries also need to have in place certain customs and institutional settings, like proper medical infrastructure and efficient organizational systems, for opt-out legislation to be effective. In fact, the introduction of presumed consent legislation in France and Brazil had adverse effects because France and Brazil failed to build the necessary social support and organization of processes, perhaps damaging trust between doctors caring for patients at the end of life and their families (Bramhall 2011).

These other factors are probably responsible for variations and outliers in the data in Table 1: The US and UK, despite being opt-in regimes, had relatively high rates of 26.65 and 20.61 deceased donors pmp in 2014 respectively; in these wealthier, aging countries demand for organ transplants is greater, and both countries have better infrastructure and organizational systems to supply donor organs and transplantations. By contrast, there are opt-out countries like Chile, Greece and Turkey that had relatively low numbers of deceased donors in 2014, perhaps due to insufficient support and infrastructure, as well as cultures that disfavor and mistrust donation and transplantation activities.

### Policy implications

When deciding on the implementation of consent default legislation, policymakers have to consider that results of observational studies using macro data do not necessarily imply that opt-out legislation is the single, “silver bullet” cause of increased donation rates. In the light of theoretical considerations and the empirical evidence presented above, supporters of presumed consent systems argue that switching to a presumed consent system could increase the supply of donated organs cost-effectively. It could be a solution that is more politically feasible than other methods, like introducing financial

incentives for organ donor registrants or their families, by offering payment to living donors; or prioritizing assignment of organs to donor registrants (a policy referred to by Schwindt and Vining as “the mutual insurance pool”) (Cohen 1989; Hansmann 1989; Schwindt and Vining 1998; Howard 2007). The fact that legislative defaults would not involve financial gain or incentivize an individual to register against personal, moral, or religious beliefs means that an opt-out rule could be more ethical. Additionally, in countries where most people are in favor of organ donation and would prefer to donate as indicated by survey results, such as the US, then changing to an opt-out system would align with more people’s preferences, while removing the costs of opting out for them. Thus presumed consent legislation could help solve shortages in donated organs, with the social benefits outweighing the costs.

Potential drawbacks to an opt-out default also arise. Some individuals who do not wish to register as donors would not have the awareness or information to opt-out; Johnson and Goldstein’s (2003, 2004) articles account for errors in which individuals who do not intend to donate are incorrectly categorized as donors. Assuming that people’s preferences toward organ donation are fluid rather than fixed, as Johnson and Goldstein do, whether or not it is ethical to use policy defaults to shape people’s attitudes, behavior and choices is questionable. There could also be difficulties in enforcing opt-out legislation consistently within a country due to legal, political or cultural differences between states or provinces.

Countries should consider the adoption of a presumed consent law as a possible way to alleviate organ shortages. However, the potential effects of such a proposal are nuanced. Historical observations show that it is important to consider whether the necessary social conditions are in place, and any change in the consent default should occur in conjunction with other strategies like increasing transplant capacity or improving the ability to identify and recruit potential donors in order to be effective.

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Table 1

## Organ donation and transplantation rates, 2014

	Opt-in or opt-out	Actual deceased donors (pmp) <sup>d)</sup>	Number of deceased organ transplantations (pmp) <sup>d)</sup>	Number of living organ transplantations (pmp) <sup>d)</sup>	Number of total organ transplantations (pmp) <sup>d)</sup>	Living kidney transplants (pmp)	Living liver transplants (pmp)	Deceased organ transplantations out of total
Austria	Opt-out <sup>a)</sup>	24.94	86.35	9.06	95.41	8.35	0.71	90.5%
Belgium	Opt-out <sup>a)</sup>	26.94	75.22	9.64	84.86	6.04	3.60	88.6%
Czech Republic	Opt-out <sup>a)</sup>	24.39	72.14	6.08	78.22	5.89	0.19	92.2%
Denmark	Opt-in <sup>a)</sup>	14.29	44.10	19.64	63.75	19.64		69.2%
Finland	Opt-out <sup>a)</sup>	22.41	63.33	2.78	66.11	2.78		95.8%
France	Opt-out <sup>a)</sup>	25.93	74.98	8.15	83.13	7.96	0.19	90.2%
Germany	Opt-in <sup>a)</sup>	10.45	38.37	8.20	46.57	7.50	0.70	82.4%
Greece	Opt-out <sup>a)</sup>	4.50	11.63	3.78	15.41	3.78		75.5%
Hungary	Opt-out <sup>a)</sup>	20.51	49.29	4.65	53.94	4.65		91.4%
Ireland	Opt-in <sup>a)</sup>	13.40	44.89	8.51	53.40	8.51		84.1%
Italy	Opt-out <sup>a)</sup>	22.65	49.82	4.37	54.19	4.11	0.26	91.9%
Latvia	Opt-out <sup>a)</sup>	14.50	27.00	3.50	30.50	3.50		88.5%
Netherlands	Opt-in <sup>a)</sup>	16.79	48.15	31.97	80.12	31.79	0.18	60.1%
Poland	Opt-out <sup>a)</sup>	15.55	40.89	2.23	43.12	1.44	0.79	94.8%
Portugal	Opt-out <sup>a)</sup>	27.26	64.16	5.56	69.72	5.09	0.47	92.0%
Slovak Republic	Opt-out <sup>a)</sup>	11.64	27.27	2.73	30.00	2.73		90.9%
Slovenia	Opt-out <sup>b)</sup>	20.95	56.67		56.67			100.0%
Spain	Opt-out <sup>a)</sup>	35.71	83.14	9.43	92.57	8.98	0.45	89.8%
Sweden	Opt-out <sup>a)</sup>	17.29	66.45	16.36	82.81	15.73	0.63	80.2%
United Kingdom	Opt-in <sup>a)</sup>	20.61	57.46	17.78	75.24	17.28	0.50	76.4%
Norway	Opt-out <sup>b)</sup>	22.75	79.22	13.33	92.55	13.33		85.6%
Switzerland	Opt-in <sup>c)</sup>	14.27	47.80	15.00	62.80	14.63	0.37	76.1%
Turkey	Opt-out <sup>b)</sup>	5.37	14.24	42.09	56.33	30.32	11.77	25.3%
Australia	Opt-in <sup>a)</sup>	16.02	49.37	11.35	60.72	11.31	0.04	81.3%
Canada	Opt-in <sup>a)</sup>	16.65	50.31	15.24	65.55	12.73	2.51	76.8%
Chile	Opt-out <sup>b)</sup>	6.91	19.83	3.82	23.65	3.31	0.51	83.8%
Japan	Opt-in <sup>a)</sup>	0.61	2.36	14.87	17.23	11.58	3.29	13.7%
Mexico	Opt-in <sup>b)</sup>	3.36	7.48	15.09	22.57	15.04	0.05	33.1%
New Zealand	Opt-in <sup>a)</sup>	10.00	30.43	16.74	47.17	15.65	1.09	64.5%
United States	Opt-in <sup>a)</sup>	26.65	75.83	17.99	93.82	17.16	0.83	80.8%
Opt-in mean (pmp)		13.59	41.38	16.03	57.41			66.5%
Opt-out mean (pmp)		19.46	53.42	8.20	61.62			86.0%
Opt-in median		14.28	46.35	15.17	61.76			
Opt-out median		21.68	60.00	5.11	61.39			

Empty cells: Data not available; pmp: „per million inhabitants“; Living transplantations include living kidney transplants and living liver transplants.

Sources: <sup>a)</sup> Shepherd, O'Carroll and Ferguson (2014). <http://bmmedicine.biomedcentral.com/articles/10.1186/s12916-014-0134-4#Sec14>; <sup>b)</sup> WHO (2014). <http://www.who.int/bulletin/volumes/93/3/14-139535/en/>;

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