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Consent Model, Opt-in/Opt-out System, and Organ Donation Rates in European Union Countries

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Abstract

Introduction: The impact of a system for organ donation consent is unlikely to explain the variation between EU countries in organ donation rates per million population (pmp). The shortage of organs for transplantation, the increased number of patients on the waiting list for organs determined to find new strategies to reduce the gap between demand and availability. In the EU countries, deceased organ donation operates under an opt-in (informed or voluntary consent) or opt-out (presumed consent) system of donation. The majority of EU countries have adopted the opt-out consent system, and it is suggested that this type of legislation can play an essential role in increasing donation rates. *Materials and methods*: The number of deceased donors was obtained from the International Registry in Organ Donation and Transplantation (IRODaT) database in August 2019 as summary data. We used this data for secondary analysis for the years 2013-2017 through descriptive and inferential statistics. Levene's test for equality of variances was used to measure the statistical difference between opt-in and opt-out system donation rates. The comparison between the 28 European Union's (EU) countries was made according to the consent system. The donation rate per million population (pmp) and actual deceased donors between the EU countries who have adopted opt-in consent system (8 countries (28.58%) namely Denmark, Netherlands, Germany, Romania, UK, Ireland, Lithuania, Malta), and countries with opt-out consent system (20 countries (71.42%), namely Sweden, Poland, Austria, France, Spain, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Italy, Latvia, Luxembourg, Portugal, Slovakia, and Slovenia) was evaluated. *Results*: In countries that adopted an opt-out system, the pmp mean was 20.39, while in the countries with an opt-in, a means pmp value of 15.97 was observed. However, the difference was not found statistically significant ($p>0.05$). *Conclusion*: The introduction of the opt-out donation system is likely to increase the number of deceased organ donors, but the role of other factors that can influence the donation rate needs to be evaluated.

Keywords: Tissue and Organ Procurement; Donation Consent; Donor Selection

Introduction

The gap between the number of patients on the waiting lists and the organs available for transplantation has grown in the last decades, which led to an increase of shortage for transplantable organs. The development of transplant medicine has saved many lives, but there are still thousands of patients dying while on waiting lists.

Organ shortage has become a significant policy issue worldwide, and efforts are done to increase deceased donation rates. The organ procurement system can be a solution to this problem, from a legislative perspective. Because organ donation rates are almost twice as high in some countries as in others, many studies have been conducted to explain this discrepancy [1–3]. Basically, in the European Union (EU) countries, two consent systems can be distinguished, namely the opt-in system and opt-out system.

Organ procurement in the opt-in system, informed or voluntary consent, individuals are required to take an explicit affirmative action to become donors by recording their will, during life time, in donors register. The individuals who are not registered in the system are assumed not to donate their organs after death, but the family could decide on or against donation [4]. This practice is considered to place additional burden and stress of decision making on the relatives and families of the deceased.

Organ procurement in the opt-out system, presumed consent, considers all members of society as potential donors, individuals should explicitly state that they do not wish to donate their organs, otherwise, they are considered as donors [5]. Presumed consent, opt-out system, may be either "soft opt-out" or "hard opt-out". In the "soft opt-out system", the family of a deceased individual who has not opted-out is asked and may refuse to donate organs. A soft opt-out system is used in Spain and France. In the "hard opt-out system", used in Austria, families of an individual who has not opted-out during his/her lifetime cannot refuse organ donation.

Studies comparing opt-in and opt-out systems have generally suggested higher donation and transplantation rates in countries with an opt-out organ procurement system [6–8]. Examples of failure of the opt-out consent in the improvement of the donation and transplantation rates also exist in France [9]. Opt-in countries switching to opt-out systems for organ donation but not guarantee to an automatic increase in organ donation and transplantation rates exist, although historically some countries have observed increases after the introduction of presumed consent system, such as Belgium [10].

Most of the EU countries, twenty from twenty-eight, have adopted the opt-out system, presumed consent legislation, and this change in legislation is suggested it has an important role in increasing donation rates. For any organ donation system to be effective, it requires a well-organized infrastructure, organizational and structural underpinned irrespective of legislation for any of the systems opt-in or opt-out. Spanish system of organ donation has long been considered to be the "gold standard" of deceased organ donation, organ donation rate increase in Spain from 14.3 pmp (per million population) in 1989 to 33.6 in 1999, through a national approach to the management of organ donation and transplantation, the Spanish National Transplant Organization [11].

Just the opt-out system alone is unlikely to explain the variation in organ donation rates between EU countries, a combination of other factors it is also significant. Legislation, transplantation system, and infrastructure, as well as underlying public attitudes to and awareness of organ donation and transplantation, may all play an important role [12]. Ethical issues, socio-cultural, and religious aspects can also significantly influence the donation rate [13].

The aim of this study was to determine if there is a relationship between the donation system and the donation rate in the EU countries.

Material and Method

Secondary data analysis was done on data obtained from the European annual reports, International Registry on Organ Donation and Transplantation-IRODaT [14]. Data were collected in August 2019 from the official website as summary data for the years 2013 to 2017. Descriptive and inferential statistics were carried out through the IBM SPSS statistical software (version 24). Levene's

test for equality of variances (inferential statistic used to assess the equality of variances for a variable calculated for two or more groups) and T-test for equality of means (statistical hypothesis test used to determine if two population means are equal) were performed to measure the statistical difference between opt-in and opt-out system donation rates. A p-value less than 0.05 indicated a significant statistical difference, opposite, a p-value over 0.05 indicated a nonsignificant difference.

The comparison between the 28 members states was made according to the consent system. In this study, we decided to compare the donation rate per million population (pmp) and actual deceased donors between EU countries with an opt-in consent system (8 countries, 28.58%) as compared to the countries with opt-out consent system (20 countries, 71.42%). The countries with an opt-in consent system regarding the donation are Denmark, The Netherlands, Germany, Romania, UK, Ireland, Lithuania, and Malta. The countries with an opt-out consent system are Sweden, Poland, Austria, France, Spain, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Italy, Latvia, Luxembourg, Portugal, Slovakia, and Slovenia.

Results and Discussion

Different patterns were observed in regards of the donation rate among countries with an opt-in system, with decrease for Denmark and Ireland, fluctuations for Germany, Lithuania, and Malta and increases of the donation rate for all others (Table 1).

Table 1. Opt-in system donation rates expressed as actual deceased donors – the integer number and the donation rate (pmp) – the value in round brackets

	2017	2016	2015	2014	2013	Mean
Denmark	103 (17.46)	100 (17.09)	87 (15.10)	80 (13.96)	58 (10.16)	85.60 (14.75)
Germany	797 (9.70)	857 (10.40)	877 (10.80)	864 (10.70)	876 (10.90)	854.20 (10.50)
Ireland	99 (20.8)	77 (16.18)	81 (17.70)	63 (13.8)	86 (18.81)	81.20 (17.46)
Lithuania	40 (14.30)	61 (21.03)	56 (19.30)	31 (10.30)	50 (16.70)	47.60 (16.33)
Malta	12 (30.00)	10 (25.00)	6 (15.00)	12 (28.60)	14 (34.00)	10.80 (26.53)
Netherlands	258 (15.18)	250 (14.71)	265 (15.70)	271 (16.10)	255 (15.26)	259.80 (15.39)
Romania	65 (3.25)	124 (6.20)	113 (5.65)	138 (6.90)	132 (6.60)	114.40 (5.72)
United Kingdom	1492 (23.05)	1401 (21.44)	1311 (20.20)	1309 (20.40)	1323 (20.77)	1367.20 (21.16)

The two axes (Figure 1) represents the evolution of opt-in system donation rates from 2013 to 2017. Figure 2 represents the evolution of opt-out system donation rates from 2013 to 2017

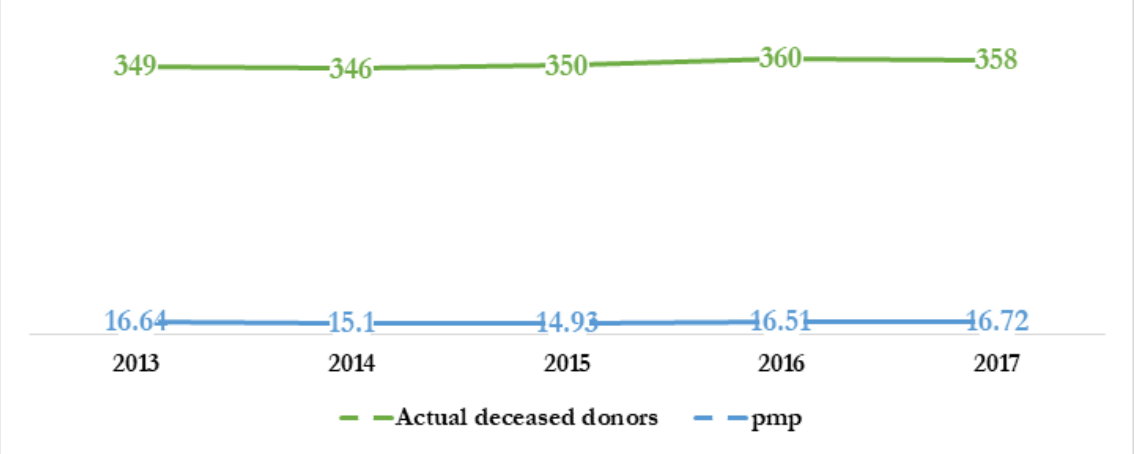

Figure 1. Opt-in system: average of actual decesed donors and donation rates from 2013 to 2017. The OY axis represents the pmp mean and the actual deceased donors mean.

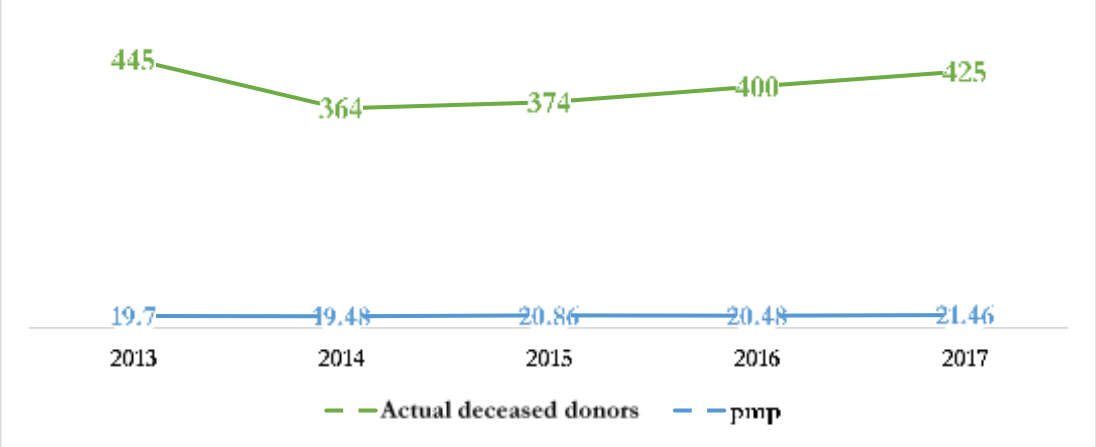

Figure 2. Opt-out system: average of actual decesed donors and donation rates from 2013 to 2017. The OY axis represents the pmp mean and the actual deceased donors mean.

A similar pattern as increased, fluctuations or decrease of the actual deceased and donation rate is also observed in the group of countries with an opt-out system results (Table 2).

Table 2. Opt-out system donation rates expressed as actual deceased donors – the integer number and the donation rate (pmp) – the value in round brackets

	2017	2016	2015	2014	2013	Mean
Austria	217 (24.70)	217 (24.90)	208 (24.20)	217 (25.5)	208 (24.60)	575.40 (24.78)
Belgium	380 (33.62)	351 (31.06)	365 (32.40)	300 (26.80)	335 (29.90)	346.20 (30.76)
Bulgaria	43 (6.01)	39 (5.57)	44 (6.29)	38 (5.43)	21 (3.00)	37.00 (5.26)
Croatia	142 (33.00)	166 (38.60)	169 (39.00)	151 (35.00)	152 (35.00)	156.00 (36.12)
Cyprus	10 (11.69)	4 (3.33)	3 (3.88)	5 (6.47)	6 (7.76)	5.60 (6.63)
Czech Republic	259 (25.51)	262 (25.00)	246 (23.40)	276 (24.40)	218 (20.57)	252.20 (23.78)
Estonia	18 (13.85)	22 (16.92)	24 (17.59)	20 (15.20)	32 (24.40)	23.20 (17.59)
Finland	118 (21.41)	136 (24.72)	127 (23.50)	121 (22.12)	96 (17.67)	119.60 (21.88)
France	1933 (29.74)	1859 (28.73)	1809 (28.10)	1742 (26.50)	1627 (25.50)	1794.00 (27.21)
Greece	67 (5.98)	51 (4.68)	39 (3.50)	49 (4.50)	62 (5.60)	53.60 (4.85)
Hungary	159 (16.21)	182 (18.51)	178 (18.00)	203 (20.55)	155 (15.61)	175.40 (17.78)
Italy	1714 (28.20)	1478 (24.30)	1369 (22.52)	1381 (23.10)	1321 (22.23)	1412.60 (24.07)
Latvia	24 (12.31)	30 (15.00)	37 (18.80)	29 (15.30)	34 (17.00)	30.80 (15.68)
Luxembourg	9 (15.80)	3 (5.0)	3 (10.90)	4 (7.30)	8 (14.90)	5.40 (10.78)
Poland	560 (14.57)	542 (14.10)	526 (13.66)	594 (15.44)	593 (15.40)	563.00 (14.63)
Portugal	351 (34.01)	337 (32.6)	319 (30.90)	289 (27.70)	295 (28.30)	318.20 (30.70)
Slovakia	86 (15.8)	72 (13.26)	94 (17.32)	64 (11.80)	60 (11.08)	75.20 (13.85)
Slovenia	43 (20.87)	42 (20.39)	55 (26.70)	47 (22.8)	50 (24.3)	47.40 (23.01)
Spain	2182 (46.90)	2018 (43.40)	1805 (39.70)	1682 (36.00)	1655 (35.12)	1864.40 (40.32)
Sweden	192 (19.00)	195 (19.57)	169 (16.90)	166 (17.12)	152 (16.00)	174.80 (17.72)

No statistically significant difference were observed among different years (Table 3) or among EU countries with different donation systems (Table 4).

Our analysis indicates that the apparent relationship between consent system and organ donation rates does not show a statistically significant difference ($p>0.05$) (Table 3) and it should also be discussed from the point of view of other factors that influence this process, the role of the organ procurement organizations, the capacity of the transplant system (medical staff trained in this regard), availability of potential donors, wealth and investment in health care and underlying public attitudes may all have a practical important role.

Table 3. Opt-in vs opt-out donation rates per year. The evolution of the values obtained for the countries with an opt-out system over the five years analyzed.

Actual deceased organ donors	Levene's Test for Equality of Variances		t-test for Equality of Means			
	F	p-value	t	Mean Difference	95% CI	
					Lower	Upper
2017 (pmp)	0.917	0.347	-1.14	-4.74	-13.27	3.79
2016 (pmp)	2.974	0.097	-0.94	-3.98	-12.68	4.73
2015 (pmp)	4.513	0.053	-1.54	-5.93	-13.83	1.97
2014 (pmp)	1.831	0.188	-1.20	-4.38	-11.87	3.11
2013 (pmp)	0.411	0.527	-0.83	-3.06	-10.67	4.55

Table 4. Opt-in vs opt-out donation rates: means comparison

Type of consent	Mean	n	StdDev	Mean Difference	F	p-value
Opt-in	15.98	8	6.29	-4.42	2.620	0.118
Opt-out	20.40	20	9.83			
Total	19.13	28	9.08			

Presumed consent alone it cannot automatically lead to a significant increase in the donation rate, (Table 4) legal shifting must be accompanied by infrastructural changes, and most important by political willingness. Non-legislative measures should also be considered, general population trust in the national health system, ethical issues, religious aspects and general attitude towards organ donation.

Donation rate has a multi-causal influence, only the adoption of the opt-out syste has no effect on the number of donors, as has been shown in other recent studies [2, 7].

Very good results to increase the donation rate were obtained in countries, such as Spain, after a long and strong investmentin public education, as well in special training programs for intensive care nurses and doctors [3].

At least two limitation of our study can be underline. First, this study evaluated strictely the numbers ; a study on the motivation to become a donor could bring more inside regarding the organ donations.To answer the question "Would you like to be a donor is case of sudden dead?" need to be investigated in each EU country to go outside the national policies. Second, no consideration was done regarding the living donors, which is another option to increase dodation rates.

A statistical analysis for each procured organ could demonstrate if a particular organ donation system records a higher value for organ donation rates.

Conflict of Interest

The authors declare that they have no conflict of interest.

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