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ORIGINAL ARTICLE

Opting-out systems: no guarantee for higher donation rates

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Summary

There are considerable differences in the number of organ donations between countries. It is assumed that opting-out systems have a significantly positive impact on the national organ donation rate. The aim of our study was to establish whether different consent systems explain the difference in organ donation rates between countries when taking into account the difference in relevant mortality rates. For this study, we compared data on donation and relevant mortality rates for 10 different countries as well as information on the existing consent systems. This international comparative study shows that there is a strong correlation between mortality rates and donation rates (Spearman's $\rho = 0.81$ ($P < 0.01$). International comparative legal research has shown that the differences between decision systems are marginal. When the national organ donation rates are corrected for mortality rates, these findings are confirmed: the donor efficiency rate shows that opting-out systems do not automatically guarantee higher donation rates than opting-in systems.

Introduction

There are considerable differences in the number of organ donations when countries are compared. And while the need for donor organs in every country is increasing, the numbers of organ donations have remained steady during the last years or have even decreased [1–3]. Because some countries have organ donation rates that are almost twice as high as in others, studies have been conducted to explain this discrepancy and to find a solution to reduce the differences [4,5].

Because organ donation is a process with several stages, there are different ways to increase the *post mortem* organ donation rates [6,7]. Examples of initiatives to increase the organ donation rates are: the Spanish model for organ donation, the use of the nonheartbeating donor pool, and the European Donor Hospital Education Programme.

An important and much-discussed cause of loss of donors is the absence of consent for *post mortem* organ donation [8]. Basically, two kinds of consent systems can be distinguished: systems of explicit consent and systems of presumed consent. In the former, the donor himself has to authorize organ removal after his death in the form of an advance directive or donor codicil, or by filling in a form to record consent in a national registry. In the presumed consent system, explicit consent is not required: it is sufficient that the deceased person did not object during life (according to national law) and therefore consent is presumed. The absence of explicit consent is by-passed by presuming the consent of the potential donor.

Because of its reliance on explicit consent, the first kind of system is also known as an opting-in system, while presumed consent systems are characterized as opting-out systems [9]. According to Gevers *et al.*, countries may differ in their laws concerning consent systems, but in practice differences turn out to be much smaller because of the role of the next of kin.

In theory, if an opting-out system is strictly applied it should result in more donations. This is based on the assumption that the group of people who make an objection to organ donation under an opting-out system is smaller than the group of people who do not register consent under an opting-in system [10]. As shown in Table 1, high-rate countries have an opting-out system.

Table 1. Organ donation rates in 10 European countries in 2002.

	Per million inhabitants*	Consent system[16]
Spain	33.7	Opting-out
Austria	24.3	Opting-out
Belgium	21.9	Opting-out
France	20.0	Opting-out
Italy	18.1	Opting-out
Germany	12.4	Opting-in
The Netherlands	13.6	Opting-in
UK	13.1	Opting-out
Sweden	11.0	Opting-out
Switzerland	10.4	Opting-in

*The rates shown comply with the definition of the Council of Europe: An organ donor is effectuated if 'at least one solid organ has been retrieved for the purpose of organ transplantation'.

This seems to endorse the opinion that opting-out systems have a significantly positive impact on the national organ donation rate, an opinion already expressed by many authors [2,10–14]. However, there is good reason to doubt that this is indeed the case [7].

Like other countries, the Netherlands has made various efforts to increase the number of organ donations. These include, among other initiatives, a campaign among the general public for registration as a consenting donor in the national register, introducing support plans for Dutch hospitals and allowing nonheartbeating organ donation. Until now, these measures did not result in a significant increase in national organ donation rates.

As several studies state that opting-out systems have a positive impact on the number of donor organs [12,13,15], the question has been raised in the Netherlands whether the consent system for *post mortem* organ removal (laid down in the Organ Donation Act of 1998) should be changed. To answer that question, an extensive study has been carried out, including a survey of attitudes in the Dutch population on organ donation, an analysis of the practice of organ retrieval in Dutch hospitals, as well as an international comparative analysis of the consent systems in 10 European countries [16].

In order to ascertain whether consent systems influence the output of the organ donation process (the organ donation rates), the input (mortality rate) also has to be taken into account. Only persons who have died meeting specific medical conditions are initially suitable as an organ donor. This mortality rate which is relevant for organ donation is the first step of the process of organ donation. Therefore, the Dutch study included an international comparison of relevant mortality and donation rates in 10 European countries in order to identify the relative importance of the consent systems as a factor influencing the availability of organs.

The aim of our study was to establish whether different consent systems explain the difference in organ donation rates between countries when taking into account the difference in relevant mortality rates.

Material and methods

For this study, we used data on donation rates and relevant mortality rates for 10 different countries (Table 2) as well as information on the existing consent systems in these countries. To restrict the number of confounding factors, we chose to compare only countries which share the same historical background and have more or less the same status of health care systems.

The national organ donation rates were derived from the national organ transplant centers and meet the definition used by the Council of Europe: an organ donor is effectuated if 'at least one solid organ has been retrieved for the purpose of organ transplantation'. We focused on the period 2000–2002, in which no major fluctuations in organ donation rates were observed. To correct for random fluctuations between years, we used three-year-means (Table 2).

This study focuses on the first factor of relevance in the donor procurement process, which is the number of people who die in a mortality category specific to organ donation. These relevant mortality rates of 10 European countries were derived from the World Health Organization's Health For All Database.

According to the annual reports of each national transplant center, approximately 80% of the deceased who

Table 2. Three year mean organ donation and mortality rates for 10 European countries.

	Three year mean organ donation rates* (per million inhabitants)	Three year mean mortality rates† for organ donation (per million inhabitants)
Spain	33.8	309
Austria	23.5	298
Belgium	23.0	343
France	18.3	330
Italy	16.8	246
UK	13.2	243
Netherlands (I)	13.0	187
Germany (I)	12.6	240
Switzerland (I)	12.5	195
Sweden	11.3	240

*The rates shown comply with the definition of the Council of Europe: 'if at least one solid organ has been retrieved for the purpose of organ transplantation' [21].
†Mortality rates for CVA and (traffic) accidents 0–65 years.
I indicates that this country has an opting-in system.

become organ donors died of a cerebral vascular accident (CVA) or (traffic) accident. That is why these mortality categories play an important role in the effectuation of a potential organ donor and we have therefore focused on these categories.

The WHO's Health for All Database was considered the best suitable source for obtaining mortality rates for international comparison, because it is a uniform database which contains the mortality rates per category per country. The mortality rates are based on the international Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10). The database only provides the mortality rates in two groups: 0–65 years or all ages. As approximately 80% of the effectuated donors have died of a CVA or (traffic) accident and are not older than 65, this study presents the mortality rates [CVA + (traffic) accident] for this group only.

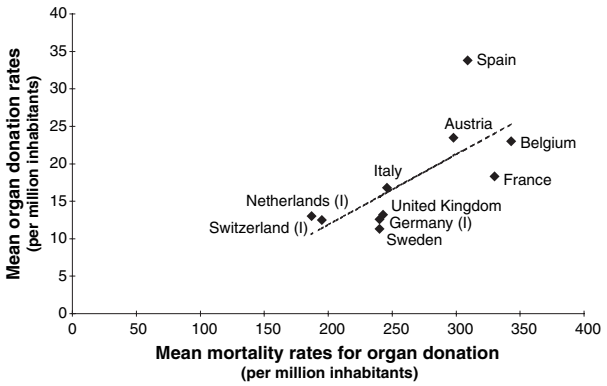
To avoid extremes, an average mortality rate over the three most recent available years with complete data is used (Table 2). For most countries, this was the period 1999–2001, with the exception of Belgium (1995–1997).

The correlation between mortality rates and donation rates was calculated using the Spearman's test. To test the relationship between the different systems and the rates for mortality, donation, and donor efficiency, a *t*-test was performed.

The information about the consent systems of the 10 European countries used in this study is derived from the international comparative analysis of these consent systems by Gevers *et al.* [9].

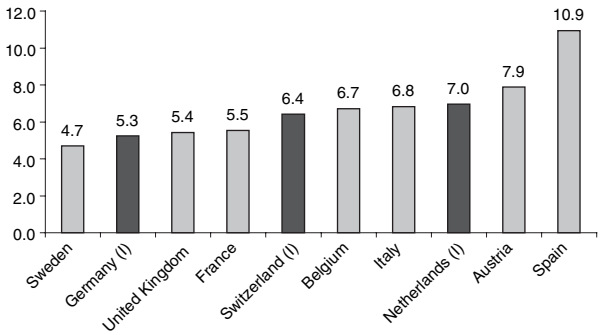
Results

The relationship between the average donation rate and the relevant mortality for organ donation is shown in Fig. 1.



(I) indicates that this country has an opting-in system

Figure 1 Relevant mortality rate and average donation rate per million inhabitants.



(I) indicates that this country has an opting-in system

Figure 2 The donor efficiency rate.

There is a strong correlation between the donation rates and the mortality rates which are relevant for organ donation [Spearman's $\rho = 0.81$ $(P < 0.01)$]. Countries with low donation rates usually have low mortality rates relevant for organ donation, while countries with high donation rates have high relevant mortality rates.

To determine the influence of other factors on the difference in the donation rates, these rates should be corrected for the differences in mortality rates. Only after this correction is it possible to ascertain any influence of factors other than mortality. The donor efficiency rate reflects the number of organ donors as a percentage of the mortality for organ donation. Figure 2 shows that countries with an opting-in system vary in their donor efficiency rate. This variability is also found in the countries with an opting-out system, which indicates that there is no correlation between consent systems and organ donation rates. This finding is confirmed by the *t*-test. According to the results of this test, there is no relation between the different systems and the efficiency rates. In other words, when donation rates are controlled for differences in relevant mortality there is no significant influence of the systems on these rates.

Discussion

Our analysis indicates that the apparent relationship between consent systems and organ donation rates disappears after controlling for difference in relevant mortality.

Gevers *et al.* have shown that countries may differ in their laws concerning consent systems, but in practice differences turn out to be much smaller. In their analysis of the national transplantation laws, and interviews with several contacts in these countries, they have shown that relatives always seem to play a certain role in the opting-out systems and that in practice these systems do not always work strictly as such.

In practice, there seems to be a need on behalf of the doctor concerned to involve the next of kin if an explicit intention by the deceased is lacking [9,17]. Even if it is legally admissible not to involve relatives for an organ donation, there is no country that does not give them a role in the organ donation process. In Belgium, France, Italy and Sweden relatives can voice an objection. In Austria, Germany, the Netherlands, Switzerland, Spain, and the UK relatives are asked to give their consent. Obviously the opting-out systems in practice in Austria, Spain and the UK are less strict than one would expect according to the law. This observation may explain the lack of difference between consent systems in organ donation rates as shown in Fig. 2 of this study.

To conduct an international comparison of national organ procurement systems, a number of difficulties must be confronted. A dramatic data reduction is necessary to study the impact of consent systems on organ procurement rates. Even disregarding aspects that are unique to a country's procurement system such as cultural differences and the influence of state's support in higher procurement performance regarding organization, educational and economical aspects, one needs to identify the relevant mortality rates. Unfortunately, at this moment there is no reliable and comparable data on cultural, organizational, educational, and economical data available. Moreover, it will be very difficult to obtain such data which can be compared on an international level. Therefore, we did not specify our analysis to the different initiatives taking place in some countries, such as the Spanish model for organ donation, or the use of nonheartbeating donations.

Another issue for international comparative studies is the need for the use of the same terminology for different steps in the organ donation process [18]. It is therefore essential to verify whether the numbers which are used for an international comparison meet the same definition. This has been accomplished here by requesting the national transplant centers to provide us with the organ donation rates which met the same definition.

To increase the donor pool in the Netherlands, the use of nonheartbeating donations was one of the initiatives introduced during the 1990s. In 2003, 39% of the total amount of *post mortem* organ donations consisted of nonheartbeating donations [19]. Other countries which also perform nonheartbeating donations and publish their nonheartbeating results are Spain and the UK. However, nonheartbeating donations in those countries only account for <5% of the total amount of *post mortem* organ donations.

The decision to widen the donor pool to include nonheartbeating donations was based on an assumed increase of usable organ donors in nonheartbeating mortality categories. However, so far this initiative has not resulted in a change in the mortality pattern for organ donation [20]. It seems that the initiative did not increase the donor pool, but took over a part of the heartbeating donations. Therefore, we included these cases of nonheartbeating donation in our donation rates. However, it should be noted that without the share of nonheartbeating organ donations in the Netherlands the efficiency rate shown in Fig. 2 would have been much lower. Although nonheartbeating has become a very important category of organ donors in the Netherlands, the use of this category does not change the final results of this study.

Conclusion

This international comparative study shows that there is a strong correlation between relevant mortality rates and organ donation rates [Spearman's $\rho = 0.81$ $(P < 0.01)$]. International comparative legal research has shown that the differences between decision systems are marginal. When the national organ donation rates are corrected for the mortality rates, the findings of the legal research are confirmed: the donor efficiency rate shows that opting-out systems do not automatically guarantee higher organ donation rates than opting-in systems.

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