

ORIGINAL ARTICLE

A plea for uniform European definitions for organ donor potential and family refusal rates

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Summary

Conversion of potential organ donors to actual donors is negatively influenced by family refusals. Refusal rates differ strongly among countries. Is it possible to compare refusal rates in order to be able to learn from countries with the best practices? We searched in the literature for reviews of donor potential and refusal rates for organ donation in intensive care units. We found 14 articles pertinent to this study. There is an enormous diversity among the performed studies. The definitions of potential organ donors and family refusal differed substantially. We tried to re-calculate the refusal rates. This method failed because of the influence caused by the registered will on donation in the Donor Register. We therefore calculated the *total* refusal rate. This strategy was also less satisfactory considering possible influence of the legal consent system on the approach of family. Because of lack of uniform definitions, we can conclude that the refusal rates for organ donation can not be used for a sound comparison among countries. To be able to learn from well-performing countries, it is necessary to establish uniform definitions regarding organ donation and registration of all intensive care deaths.

Introduction

In many countries, a gap exists between the number of organ donors and the number of patients on the waiting list, resulting in a long waiting time for transplantation. To quantify the donation performance in a country, the number of organ donors per million population (p.m.p) is often regarded as an important criterion. These rates differ strongly among countries and are published annually for comparison, for example by the Council of Europe [1]. The validity of comparing countries' donation rates p.m.p. has recently been discussed by Cuende *et al.* They concluded that older populations have a higher donation potential; so for comparison, donation rates should be adjusted for age [2]. Tuppin *et al.* have also discussed the difficulty of comparing international data on organ donation and organ shortage rates [3].

Countries can follow different policies on organ donation, for example organ procurement from brain death donors, from donors who have died after cardiac arrest, and from living donors. These donation policies undoubtedly affect the kidney donation and transplantation rates in the various countries.

The discussion on the use of donor rates for international comparison is interesting, because for countries with a low donation performance it is relevant to learn from countries with a better performance. However, donor rates are only indicators of the effectiveness of the donation process. Information on the process that occurs *before* donation is also relevant. As Gortmaker *et al.* established, an accurate method for estimating donor potential in hospitals and regions is to review medical records of deceased patients [4]. In this study, we focus on figures on donor potential and refusal rate for organ donation, as

conversion of potential donors to actual donors may be significantly influenced by family refusals [5–9]. The aim of our study is to investigate whether refusal rates can be compared among countries. The intention is to determine countries with the best outcomes on refusal rate in order to be able to learn from the best practices.

Methods

We searched in the literature for reviews that provided information about the definition for a potential organ donor *and* the refusal rate, and focused on studies using data from intensive care units (ICUs) in Europe, that were published from the year 2000 onwards in English. There is an enormous diversity among these studies. Some were conducted nationally with outcomes conclusive for the whole country, while others were smaller representing only a selection of deceased patients in ICUs of one or more regions in a country. The material in the articles is so heterogeneous that sound comparison becomes rather difficult. Although 22 studies are published according to our inclusion criteria, only 14 contain clear and detailed information about the definition for a potential organ donor and the refusal rate (Table 1) [5,7–27]. These 14 publications were the most exploratory material for further analysis in our study.

When more than one publication is available from a particular country, only the largest study is selected. This is the case for articles from the UK, the Netherlands, Germany, Belgium, Finland, Sweden, Italy, and Spain [5,8,9,11,17,18,25]. Because of the limited number of large studies on donor potential from European countries, we also included a major study performed in the USA by Sheehy *et al.* [6]. In total, eight selected publications originating from 11 countries were analysed in our study (Table 1).

The data on donor potential from the selected studies were not always comparable with data provided by National Transplant Agencies or Organ Procurement Organizations (OPO), as not in all countries *every* potential organ donor is referred to these agencies. Some OPOs only document referral of brain death donors after consent for donation is given. This underestimates the total number of potential donors by excluding those who were not referred because brain death was not diagnosed for example because of prior family refusal [6,11,27–29].

In this study, several steps were taken to compare the donor potential and the refusal rates among countries. The first step was to identify the definitions used for donor potential. The second step was to explore which definitions were used for the refusal rate and the influence of the Donor Register. Finally, we studied the

Table 1. Characteristics of European studies reviewing for organ donor potential and refusal rate.

No.	Study	Country	Definition potential organ donor clearly described	Definition refusal rate clearly described	Selected for our study
1	Möller <i>et al.</i> [10]	Sweden	Yes	Yes	No
2	Roels <i>et al.</i> [11]	Belgium, Finland, Switzerland, France	Yes	Yes	Yes
3	Bozzi <i>et al.</i> [12]	Italy	No	No	No
4	Procaccio <i>et al.</i> [13]	Italy	No	Yes	No
5	Pszenny <i>et al.</i> [14]	Poland	No	Yes	No
6	Wesslau <i>et al.</i> [9]	Germany	Yes	Yes	Yes
7	Gelder <i>et al.</i> [15]	Belgium	No	Yes	No
8	Polowczyk, <i>et al.</i> [16]	Poland	Yes	No	No
9	Jansen <i>et al.</i> [8]	The Netherlands	Yes	Yes	Yes
10	Barber <i>et al.</i> [5]	UK	Yes	Yes	Yes
11	Lundell <i>et al.</i> [17]	Sweden	Yes	Yes	Yes
12	Ridolfi <i>et al.</i> [18]	Italy	Yes	Yes	Yes
13	Kompanje <i>et al.</i> [19]	The Netherlands	Yes	Yes	No
14	Madsen <i>et al.</i> [7]	Denmark	No	Yes	No
15	Frutos <i>et al.</i> [20]	Spain	No	Yes	No
16	Höckerstedt <i>et al.</i> [21]	Finland	Yes	Yes	No
17	Miranda <i>et al.</i> [22]	Spain	Yes	Yes	No
18	Park <i>et al.</i> [23]	UK	Yes	Yes	No
19	Pokorna <i>et al.</i> [24]	Czech	Yes	No	No
20	Cuende <i>et al.</i> [25]	Spain	Yes	Yes	Yes
21	Pugliese <i>et al.</i> [26]	Italy	Yes	Yes	No
22	Schütt <i>et al.</i> [27]	Germany	Yes	Yes	No

possible interaction between the refusal rate and the legal context for organ donation.

Results

Source and definition of a potential organ donor

Out of the final eight publications originating from 11 countries we analysed the study population and the starting point for the definition of a potential organ donor (Table 2).

1 In the study of Roels *et al.* four countries comprising Belgium, France, Switzerland, and Finland were reviewed for potential organ donors [11]. All countries applied the same methodology, the Donor Action program, for analysing medical records. In total, 18 118 critical care deaths in 166 hospitals (381 CCUs) between January 2006 and December 2007 were reviewed. A potential organ donor was defined as a patient with no contraindications to organ donation, with signs of severe brain damage, and who met standard preconditions for brain death diagnosis.

2 In Spain, data were recorded from 42 hospitals in 1998, 62 in 1999 and 70 in 2000 [25]. Medical records of deceased patients in ICUs were internally and partly externally audited. A potential organ donor was defined as a patient who was considered encephalic death or brain death.

3 In the Southern Healthcare Region of Sweden, clinical data on all deceased patients (3760) in ICUs of 13 hospitals were recorded, between 1999 and 2004 [17]. A potential organ donor was defined as a patient diagnosed with brain death and no contraindications for organ donation.

4 The Emilia-Romagna region in Italy had a history from 1998 until 2005 of reviewing all medical records of deceased patients (10315) in 21 ICUs [18]. Potential organ donors were defined as patients with severe brain damage Glasgow Coma Scale (GCS): E1, M1, V-tube, mechanical ventilation and admitted to the ICU for more than 6 h.

5 A national potential donor audit was developed in the UK to identify the true potential for organ donation, between April 2003 and March 2005 [5]. In total, 341 ICUs from 284 hospitals participated in the study on potential organ donors. The medical records of all patients who died in the ICU were reviewed. Relating to each of the death in the ICU (46801), a form was filled in and submitted to UK Transplant. Mechanically ventilated patients, brain death diagnosed by brain stem testing and no medical contraindications to heart-beating donation were defined as potential organ donors.

6 The number of potential organ donors in the USA was analysed by reviewing medical records of deceased

patients in the area of 36 organ-procurement organizations [6]. This review took place during a 3-year period between 1997 and 1999. Sheehy *et al.* considered a patient to meet the criteria for brain death when in the medical chart any or all of the following items were found: absence of spontaneous respiration and two additional brain-stem reflexes, brain death declaration, a flat electroencephalogram, or other brain studies indicating irreversible destruction of the brain. In total, 18524 brain death potential organ donors were identified.

7 In the Netherlands, a study was performed by reviewing medical records of deceased patients (5880) in 52 ICUs [8]. The definition of a potential organ donor was divided into three sub-categories. A *potential heart-beating donor*: a patient in whom brain death was diagnosed, without medical contraindications to donation and younger than 76 years. A *possible heart-beating donor*: a patient on ventilation, with severe brain damage (GCS; E1, M1, V-tube and the absence of one or two brain-stem reflexes), under the age of 76 years with no medical contraindication to organ donation. These were patients where the brain death diagnosis was not completed because of nonmedical reasons (i.e. refusal for donation). There was also a definition for a *potential donor who died after cardiac arrest* 'Maastricht Classification category III'¹ [30]. This was a patient on mechanical ventilation, with or without severe brain damage (did not meet the criteria for brain death), an infaust prognosis, under the age of 65 years, and with no medical contraindication to organ donation.

8 In the north-east region of Germany, a form was designed to collect data of deceased patients in ICUs, filled in by physicians [9]. Data collection took place between 2002 and 2005. Only patients with primary or secondary brain damage were included in this study (2019 forms), and only returned forms were evaluated without the certainty that all relevant deaths had been reported. Wesslau *et al.* used two definitions for deceased patients with primary or secondary brain damage: *possible organ donors* were defined as those deceased for whom no medical contraindications to organ donation existed, and *potential organ donors* as those for whom the diagnosis of brain death had been initiated and/or completed and where no contraindications existed.

The definition of a potential organ donor differs sharply among the analysed studies. For example in one study, the starting point was defined as a patient with

¹ Maastricht Classification for donors who died after cardiac arrest – category I: dead on arrival; category II: unsuccessful resuscitation; category III: awaiting cardiac arrest; category IV: cardiac arrest while having brain death.

Table 2. Overview articles and the different refusal rates.

No.	Country [reference]	Population study	Starting point definition potential donor	Original refusal/consent rate, %	Definition 1: family refusal/total number of potential donors, %	Definition 2: family refusal/number of families asked for donation, %	Number of patients with objection in Donor Register	Total refusal rate, %
1	Belgium [11]	All deceased patients in 149 CCUs in 78 hospitals	Patients with severe brain damage	89.5 (consent)	8.4 (22/261)	10.5 (22/209)	NA	
2	Finland [11]	All deceased patients in 55 CCUs in 20 hospitals	Patients with severe brain damage	89.5 (consent)	9.8 (8/82)	10.5 (8/76)		
3	France [11]	All deceased patients in 136 CCUs in 37 hospitals	Patients with severe brain damage	65.7 (consent)	24.1 (237/984)	34.3 (237/691)	NA	
4	Switzerland [11]	All deceased patients in 41 CCUs in 31 hospitals	Patients with severe brain damage	76.5 (consent)	18.1 (23/127)	23.5 (23/98)		
5	Spain [25]	All deceased patients in 174 hospitals	Brain death diagnosed	16.4 (refusal)	16.4	NA		
6	Sweden [17]	All deceased patients in ICUs in the Southern Healthcare region	Brain death diagnosed	54.6 (consent)	17.5	40.5 (34/84)	46	41.2 (80/194)
7	Italy [18]	All deceased patients in ICUs in the Emilia-Romagna region	Patients with severe brain damage	29 (refusal)	NA	29		
8	UK [5]	All deceased patients in ICUs in 284 hospitals	Brain stem death diagnosed	41 (refusal)	34.3 (941/2740)	41 (941/2320)	NA	
9	USA [6]	All deceased patients in ICUs in the service areas of 36 organ procurement organizations	Brain death diagnosed or patients who met the criteria for brain death	54 (consent)	38.8 (7192/18524)	46 (7192/15500)	NA	
10	The Netherlands [8]	All deceased patients in 52 ICUs	Brain death diagnosed or patients with severe brain damage	59 (refusal)	45 (284/631)	59 (284/478)	71	56.3 (355/631)
11	Germany [9]	Deceased patients with primary or secondary brain damage in 136 ICUs in the north-east donor region	Brain death diagnosed or brain death initiated	72.5 (refusal)	38.3 (492/1285)	42.9 (492/1147)		

Re-calculated refusal rates are in bold.

CCU, critical care unit; ICU, intensive care unit; NA, information not available in article.

brain (stem) death diagnosed, but in another as a patient with severe brain damage without a complete brain death diagnosis. However, even the definition of severe brain damage varied from only a GCS of E1, M1, V-tube, to a GCS of E1, M1, V-tube *and* the absence of one or more brain-stem reflexes. Finally, potential organ donors were mainly defined as potential *heart-beating* donors, but in some countries potential donors who have died after cardiac arrest were also included.

Refusal rate for organ donation

In the reviewed articles, we found the refusal rates as presented in Fig. 1. When analysing these rates in detail two different definitions of refusal rate could generally be distinguished among the evaluated articles: the number of family refusals divided by *the total number of potential donors* (definition 1) [9,17,25], and the number of family refusals divided by *the number of families asked for donation* (definition 2) [5,6,8,11,18]. The only exception was in the article of Wesslau *et al.* from Germany where the refusal rate was defined by: the number of family refusals divided by *the number of donor losses* [9]. The reason for this high refusal rate of 72.5% in that article was the used definition, in which the potential donors who became actual donors were excluded. When family refusal was

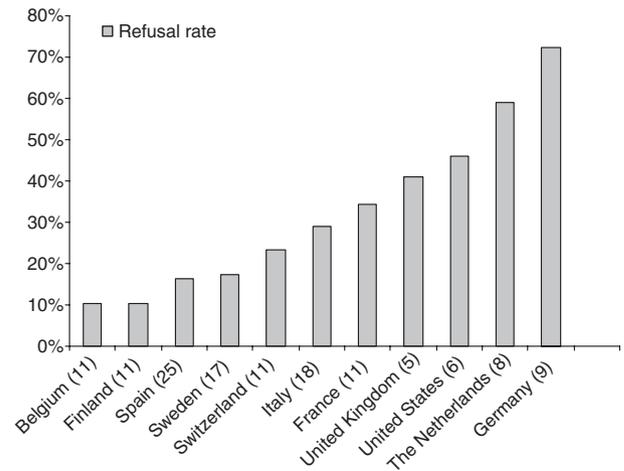


Figure 1 Refusal rates published for different countries.

calculated divided by *the total number of potential donors*, the rate dropped to 38.3% (492/1285).

From our review in the literature, it is clear that the family refusal rate differs between the two definitions for family refusal which were most frequently used. In order to compare refusal rates we tried to re-calculate the refusal rate for each study according to both definitions, with the re-calculated rates in bold (Table 2). However, some

No.	Country [reference]	Consent system	Donor Register
1	Belgium [11]	Opting-out	Donor Register since 1987; only for objection and since 2005 also for consent
2	Finland [11]	Opting-out	No Donor Register
3	France [11]	Opting-out	Donor Register since 1998; only for objection against donation
4	Switzerland [11]*	Opting-in	No Donor Register, only a donor card
5	Spain [25]	Opting-out	No Donor Register, only a donor card
6	Sweden [17]	Opting-out	Donor Register since 1995; for consent and objection and also a donor card
7	Italy [18]	Opting-out	No Donor Register, only a donor card
8	UK [5]	Opting-in	Donor Register since September 2006; registration of wishes and consent for organ donation
9	USA [6]†	Opting-in	No national Donor Register, but registries in several states and a donor card.
10	The Netherlands [8]	Opting-in	Donor Register since 1998; for consent, objection, decision by relatives or specific person
11	Germany [9]	Opting-in	No Donor Register, only a donor card

Table 3. Legal consent system and Donor Register for organ donation.

*During the study period of Roels *et al.* Switzerland had no national legislation, regulation by individual cantons was based on opting-in, opting-out or no regulation at all [11].

†The USA have no national law on organ donation, although most states follow an opting-in system [31].

articles contained insufficient data to re-calculate the family refusal rate for a definition; this is shown by the use of the abbreviation NA (not available). The percentage of family refusals in definition 1 is always lower than in definition 2, because in definition 2 the refusals are divided by a smaller group of only families who were asked for donation.

The factor that was not taken into account when calculating the refusal rates in the reviewed articles, was the registered will on donation of the deceased patient in the Donor Register (Table 3). In countries without a Donor Register the family was asked to consent for donation. In countries with a Donor Register the will of the potential donor on donation can be registered. The so called ‘will on donation’ in the Donor Register to a large extent creates the difference between the two definitions of family refusal rate in these countries. When the will on donation of a potential donor is against donation, the consent of the family is not requested. Therefore, we looked at the *family refusal rate* and the *total refusal rate* that included

the persons who registered objection for donation in the Donor Register (Fig. 2). Looking at the articles of countries with a Donor Register, we re-calculated the family refusal rate into the *total* refusal rate wherever possible (Sweden, the Netherlands) (Table 2). For most articles, however, not enough information was available to calculate this rate.

Legal consent system for organ donation and refusal rate

In the articles from countries that we reviewed in Fig. 1 two legal consent systems for organ and tissue donation can be distinguished: one with an explicit consent for donation (opting-in system) and one with a presumed consent for donation (opting-out system). In fact, in an opting-in system donation can only take place if consent is given by the donor (a signed donor card or registration in a Donor Register) or by the next of kin. In an opting-out system donation can take place when the donor did not object to donation while he was alive, so the consent was presumed (Table 3). In between these two strict definitions, there are differences in the practical use of these systems among countries.

When the legal systems are compared with the published refusal rates of the different countries from the studied articles, it seems that the refusal rate is lower in countries with an opting-out system (Fig. 3).

Discussion

Refusal rates

There are many studies on reviews of ICU deaths, although the number of national studies is small. We tried to compare the refusal rates in the reviewed articles from several countries expecting to get insightful information and reasons for the large range in refusal rates among countries. In this article a selection was made of studies with a clear definition of a potential donor and refusal rate. We analysed these definitions and found essential variation among the reviewed articles. Then we tried to re-calculate the refusal rate for each country according to the different definitions. This method still did not result in fully comparable data, because the influence of the will on donation registered in the Donor Register was not taken into account. Therefore we calculated the *total* refusal rate, including the outcome of the Donor Register. However, this strategy was also less satisfactory because of possible influence of the legal consent system on the approach of relatives. In an opting-out system, the consent to donation of the donor is presumed, so officially the relatives do not play a role in the decision-making process. On the contrary in an opting-in system, in case a positive registration of the potential donor is

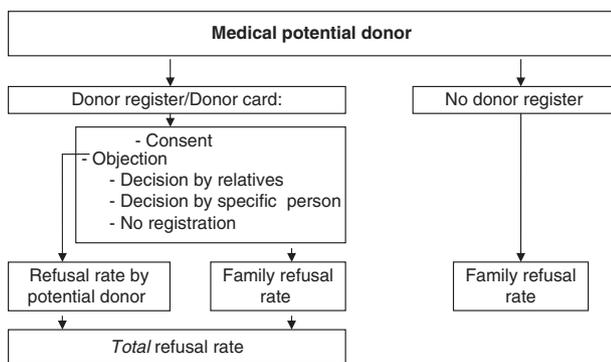


Figure 2 Family refusal rate and *total* refusal rate.

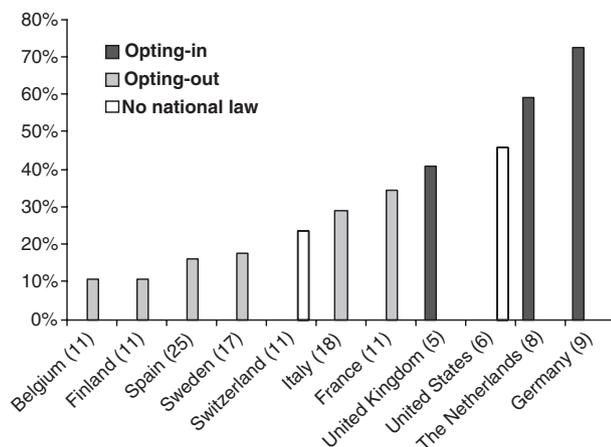


Figure 3 Consent system and refusal rate.

lacking, donation can only take place after an explicit consent of the relatives.

The explored factors negatively influenced the opportunity to come to a uniform definition of the refusal rate. Although we already expected it would be difficult to compare donor potential and refusal rates, driven by the need to learn from countries with the best practices, we extensively investigated the published definitions and tried to use same definitions for refusal rate, to finally come to the conclusion that we were unsuccessful in finding a good comparison.

A limitation in our study is that potential organ donors are not only located on the ICU. There are also publications of potential organ donors located in the accident and emergency departments, as exemplified in a study of Aubrey *et al.* [32]. For an exact evaluation and to identify every potential donor in a hospital, medical records of all hospital deaths should be reviewed, as Opdam *et al.* realised while examining the data from one state in Australia [33]. However, the number of articles reviewing donor potential except from those in the ICU is limited; therefore our study is only focused on intensive/critical care deaths.

Legal consent system

The refusal rates are used as facts in comparing the effect of the legal consent system among different countries. From Fig. 3 it appears that countries with an opting-in system have higher refusal rates than countries with an opting-out system. From our study, we can conclude that combining refusal rates from different publications of different countries in one figure, as we did as an example, is inconsistent and not useful for measuring effects of legal consent systems. With these inconsistent figures it is hard to prove that an opting-out system results in more donors. However, in Belgium and Spain rates of donation have improved since the legal system was changed into opting-out.

Organ donation rates in Europe and the influence of the legal consent system for organ donation were compared by the Netherlands Institute for Health Services Research (NIVEL) for 10 different countries [34]. The aim of their study was to establish whether differences in consent systems were responsible for the differences in the number of organ donors after correction for mortality rate. The conclusion of that study was that after donation rates were corrected for mortality rates, differences among legal consent systems were marginal and that national donation rates were not automatically higher in opting-out systems as compared with opting-in systems. Gevers *et al.* showed that although European countries have different legal consent systems for organ donation, in practice families are approached to consent

to donation even in a strict opting-out system [35]. With the above mentioned conclusions about the problems with comparing figures, the conclusions of these studies are questionable.

Other factors influencing refusal rates

Besides the factors of influence that we explored, there could be other confounders, for example the timing of the request for organ donation with the family. In the Netherlands, in practice, doctors will often discuss donation with the family of potential organ donors *before* brain death is formally diagnosed, although the donation request officially has to be made after death. Also in the case of donors who have died after cardiac arrest (category III), donation is often discussed with the family after an infaust prognosis but before a ventilator switch off procedure takes place to wait for the cardiac arrest. Physicians in the UK, Germany, Sweden, and Spain will explicitly wait to raise the issue of organ donation after (brain) (stem) death is diagnosed [5,9,17,25]. The timing of the donation request was not described in all articles and therefore the full impact on the refusal rate can not be further explored.

The kind of potential donor could also be a confounder. Besides the procurement of organs from heart-beating donors for organ transplantation, donation of organs from donors who died after cardiac arrest was performed in the UK and the Netherlands and in smaller numbers in Spain and Belgium.

Another confounder could be the number of hospitals included in the reviewed articles. While in the UK a national study was performed, in many other countries only a selection of hospitals in particular regions were included. Refusal rates can differ even among regions and particularly among hospitals.

Uniform registration of ICU deaths

Despite all discussions on the validity of numbers of potential donors and refusal rates, the fact is that there are vast differences in donation performance among countries. Therefore it remains important to come to an objective comparison among countries in order to learn from countries with the best practices. In our opinion this starts with a uniform process for the registration of all deaths in ICUs.

Initiatives have already been taken for uniform registration of deceased patients in ICUs. One method is to use the Medical Record Review as a part of the Donor Action program [36]. The methodology of reviewing all medical charts of deceased patients in ICUs is very helpful, although it is essential that data are entered in a uniform

way by all countries. In Spain, charts of all patients who died in CCUs are reviewed by transplant co-ordinators and an extra step is taken to verify data by external audits [37]. Another initiative comes from the DOPKI consortium, a European project funded by the European Commission. DOPKI recently published a methodology to estimate the potential of deceased donors and to evaluate the performance in the deceased donation process that was validated in a pilot study of 30 hospitals from 10 European countries [38]. They published a 'guide of recommendations for quality assurance programmes in the deceased donation process'. In our opinion, this guide of recommendations is an important first step in the effort to come to universal definitions within the European Union. Another important step is to find consensus on the exact starting point of what can be defined as a potential organ donor. For a 'possible deceased organ donor' (a person dying in ICU with primary or secondary brain damage), this can be reached when there is an agreement on a detailed level on severe brain damage; the required Glasgow Coma Score and the number of brainstem reflexes that are absent, as well as when to start brain death diagnosis. For comparison among countries performing donation from donors who have died after cardiac arrest, however, uniform definitions for potential of these donors should also be added. Without clarifying the exact starting point, comparison of data will still be inadequate.

Although the refusal rates can not be compared among countries as yet, it is clear that in some countries these rates are an important negative factor in the conversion of potential donors to actual donors. It is of great relevance to improve the registration of ICU deaths in general, and specifically in the use of uniform definitions for donor potential and refusal rate. When definitions of refusal rates are comparable, the large differences in these rates can hopefully be further explained which will give opportunities to learn from well-performing countries.

Authorship

NEJ: performed study, wrote the paper. BJMHK: proposed topic, wrote the paper, significant contribution in discussions. HAVL: wrote the paper, analysed data. WW: wrote the paper, significant contribution in discussions. AH: designed study, wrote the paper.

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