

A systematic literature review on the policies and economic evaluation of organ transplantations in EU

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ABSTRACT

BACKGROUND: transplantation of human organs and tissues saves many lives and restores essential functions in combination of high measurable quality indicators. In spite of the fact that organ transplants have saved thousands of lives and greatly improved the quality of life of thousands more, regrettably many people will not benefit from this therapeutic procedure.

METHODS: this review is based on economic evaluation studies published since 2000 and reviews published since 1987 for kidney, liver, lung, heart, pancreas, and small bowel transplantations that were conducted in 2010.

RESULTS: empirical evidence showed that the costs of organ transplantations have generally decreased over time due to improvements in medicine, while survival and quality of life have improved. This indicates that the cost-effectiveness of transplantation has also improved over this period.

CONCLUSIONS: cost effectiveness studies on organ transplantations could contribute to the efforts of policy makers in maximising societal health benefits by managing society's scarce resources. The differences between EU country are not only associated with different legal procedures but are also associated with social, organizational and several other factors.

Key words: Organ Transplantation; Economic evaluation; Donors' consent

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INTRODUCTION

Human organ transplantation is the therapeutic use of human organs as a substitute for one that is non-functional. The organ may come from a deceased (formerly cadaveric) or a living donor. Over the last few

decades, organ transplantation has evolved from an experimental treatment to the gold standard for a number of patients with major inefficiencies, such as renal failure. According to World Health Organisation (WHO) [1], transplantation is the transfer (engraftment) of human cells, tissues or organs from a

donor to a recipient with the aim of restoring functions in the body. When transplantation is performed between different species, it is named xenotransplantation. Transplantation of human organs and tissues saves many lives and restores essential functions in combination of high measurable quality indicators, such as life years gained and improvement in quality of life. In spite of the fact that organ transplants have saved thousands of lives and greatly improved the quality of life of thousands more, regrettably many people will not benefit from this therapeutic procedure. The severe shortage of donors across all organ categories remains one of the major constraints facing the EU members. There are wide differences in the organ donor rate in EU countries, which cannot be explained only by the differences in public attitude and mortality rates [2, 3]. Binding authorisation for organ procurement and transplantation procedures is not required in a significant number of EU countries and binding legislation on traceability and notification of adverse reactions is not in place in at least one third of the countries. The inclusion and exclusion criteria for waiting lists as well as the criteria for selecting the suitable donors are established in the majority of countries through professionals' guidelines [4-6]. The number of organ transplantations in many EU countries is increasing on a quick rate mainly due to adaptation of effective policies, transparent legal framework and due to increasing social awareness. However, there are many discrepancies in the number of transplants as well as in the number of transplantations among the countries. The main driver of the supply of transplants and thus the performance of transplantations is the number of potential donors per million people (pmp). The donors' consent which is also known as "opting in" or "opting out" system is recognised as one of the key issues in the process of organ transplantation. Basically, two types of consent to donation from deceased donors can be distinguished today in national legislations: the principle of presumed consent or "opting out" (contracting-out) and explicit consent or "opting-in" (contracting-in) [7]. In a presumed consent system, no explicit consent is required to become a potential donor. The donation procedure can be initiated, unless the deceased person had objected during life. In an explicit consent system, the donor himself needs to

consent to organ removal after death explicitly. In practice, and in the absence of such explicit consent, most laws require the deceased's next-of-kin (the nearest blood relatives of a person who has died, including the surviving spouse) to consent to post-mortem organ removal. Moreover, there are discrepancies in the way of diagnosing brain death (DBD) [8-11] in terms of criteria and in terms of the number of doctors that should justify the brain death. In addition, a low percentage of countries have a binding law for non-heartbeating donors, which results in many cases of lost transplants.

METHODS

We had proceed with a comparability analysis of the numbers of organ transplantations among those EU countries with similar geographical, economic, social and cultural profiles but with significant differences in the number of donors and organ transplantations. This systematic review was performed by PRISMA statement. The results on economic evaluation studies, published since 2000 and reviews published since 1987 for kidney, liver, lung, heart, pancreas, and small bowel transplantations, were conducted in 2010 in PubMed and in NHS Economic Evaluation Database (Centre for Reviews and Dissemination, University of York) [12]. Following key words were used to search the database for appropriate literature: "organ transplantation"[MeSH Terms] OR "organ transplantation"[All Fields] AND ("ethics"[All Fields] OR "ethics"[MeSH Terms]) AND ("policy"[MeSH Terms] OR "policy"[All Fields]) AND ("social control, formal"[MeSH Terms] OR "formal social control"[All Fields]) AND ("tissue donors"[MeSH Terms] AND "quality of life"[MeSH Terms] OR "quality of life"[All Fields]) AND ("economics"[MeSH Terms] OR "economics"[All Fields] AND ("cost-benefit analysis"[MeSH Terms] OR "cost-benefit"[All Fields] OR "cost effectiveness"[All Fields]) AND ("questionnaires"[MeSH Terms] OR "questionnaires"[All Fields] AND ("AND ("jurisprudence"[MeSH Terms] OR "jurisprudence"[All Fields]). In order, to identify the impact of the legislation on the numbers of organ donors and organ transplantations, we had refer to a survey [2, 3] conducted by the European Commission (EC), and in particular by the Directorate of General Health and

Consumer Protection in collaboration with the Public Health and Risk Assessment Directorate on legal requirements related to organ transplantation in the 25 EU Member States as well as Bulgaria, Norway, Romania and Turkey in 2003. Following the data reported on the survey [1, 3], we had proceed to a comparability analysis between EU countries that present significant gap between the supply and demand for transplants. The countries that we had focused on are selected based on similarities in the population, geographical area, culture, economic and social status. In this article, donors' consent will be a part of the comparability analysis between EU countries since there is enough empirical evidence suggesting that donors' consent is one important factor affecting the number of donors reference.

RESULTS

The search revealed 35 potentially relevant articles (Figure 1). By examining the statistics (Table 1), we notice that countries with the same number of population have significant discrepancies in the annual rate of deceased donors pmp. In particular, from this comparison

the potential of increasing the rate of donors in countries such as Greece to reach the European average that is approximately from 15 to 19 deceased donors pmp, is also obvious. The case of Portugal is known as a success case because it followed the Spanish model of organ donation for transplantation. In particular, this model is among the most effective ones mainly because it has a formal but flexible management structure which ensures that the transplant coordinators working at the grass-roots level have a sense of involvement and are accountable for performance [7, 13]. The presumed consent (Figure 2) could explain to an extent the significant discrepancies in the rate of donors among the EU countries given the multidimensional nature of the donation process. When comparing four socioeconomically comparable EU countries, donation rates pmp are nearly twice as high in Austria and Belgium, where the "opting out" system (presumed consent) is adapted compared to those in Germany and the Netherlands. Correspondingly, the number of transplants pmp is twice as high in Austria and Belgium than that in Germany and the Netherlands. Several countries with a presumed consent law, such as Belgium, Croatia, France, Poland, and Sweden, have developed a national non-donor registry to collect citizens' objections during life [8, 9]. Interestingly, in almost all

FIGURE 1

THE SEARCH STRATEGY AND FLOW DIAGRAM FOR DATABASES SEARCH

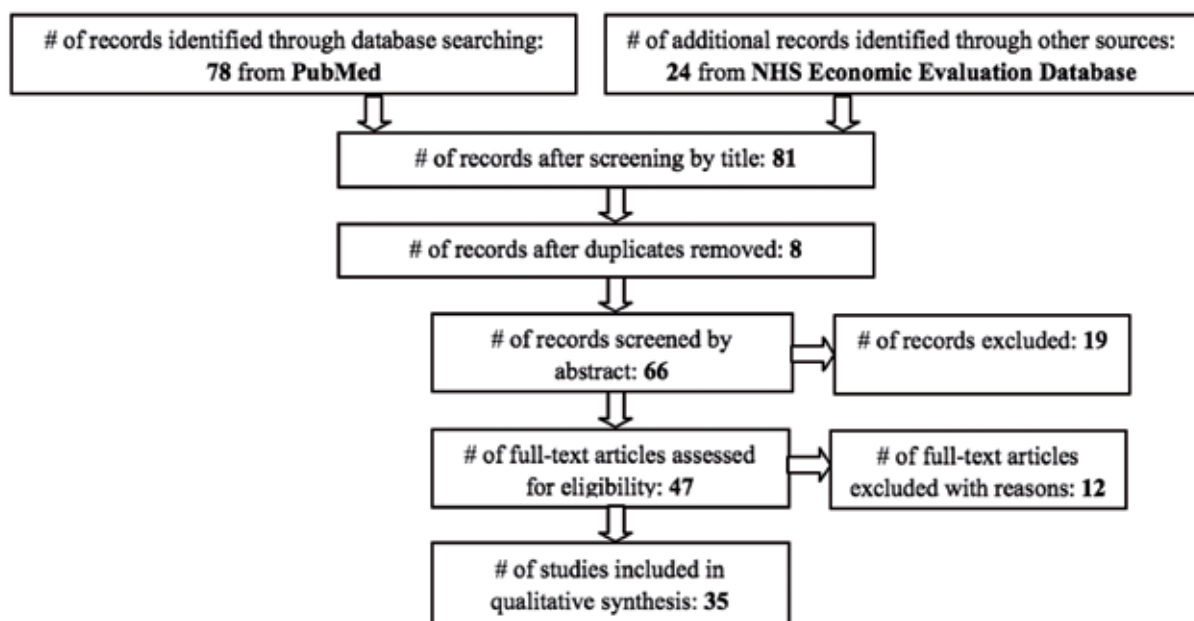
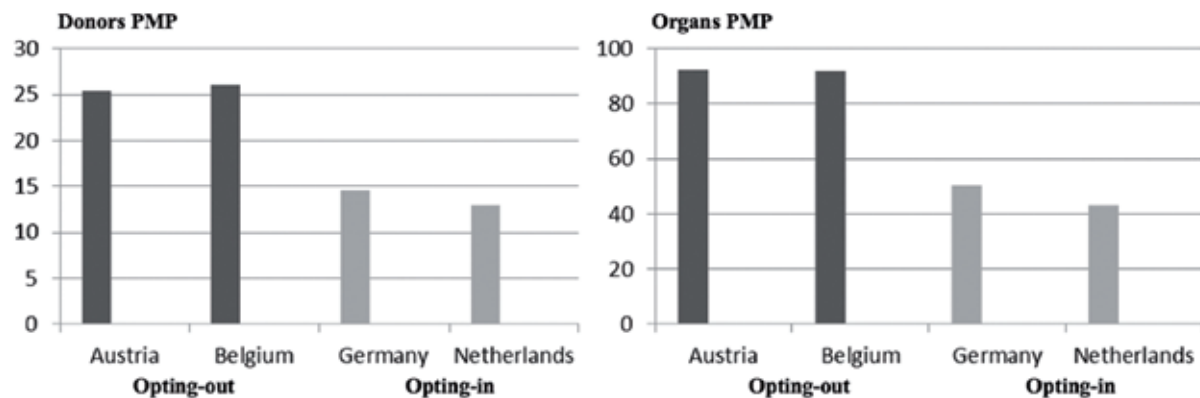


TABLE 1

COMPARABILITY ANALYSIS BETWEEN COUNTRIES WITH SIMILAR PROFILES OF POPULATION (MODIFIED BY MATESANZ R, [2])				
2009	GREECE	CZECH REPUBLIC	PORTUGAL	BELGIUM
Population	11.2	10.5	10.6	10.8
Actual deceased donors (pmp)	71 (6.3)	206 (19.6)	329 (31)	221 (20.5)
Kidney transplantation	116	346	531	428
Liver transplantation	33	102	254	222
Heart transplantation	8	80	47	68
Lung transplantation	3	22	11	90
Waiting list for kidney	983	590	2 111	866
Waiting list for liver	40-50	72	133	191
Waiting list for heart	21	79	19	58
Waiting list for lung	6	41	16	95

FIGURE 2

DECEASED DONORS AND AVAILABLE ORGANS PM (MODIFIED BY ROELS L ET AL, [7])



European countries with a presumed consent law, it is daily practice, especially in the absence of a registered will from the deceased, to approach donor families regardless of the legal situation. The families are, in this situation, not approached with a mostly confronting request to donate, but rather as an attempt to find out whether the deceased himself would have objected to donate [4, 5]. This subtle but fundamental difference in family-approach techniques between countries with an explicit consent law and those with a so-called “soft” presumed consent practice, by shifting the burden of a decision from the donor family to the donor himself, may be an important factor for explaining the significantly lower average refusal rates in the those countries with “soft opting out” systems, such as Greece (Table 2) [7]. The international figures on donation and transplantation published from Council of Europe in 2010 [2, 3], show that in Spain the annual rate

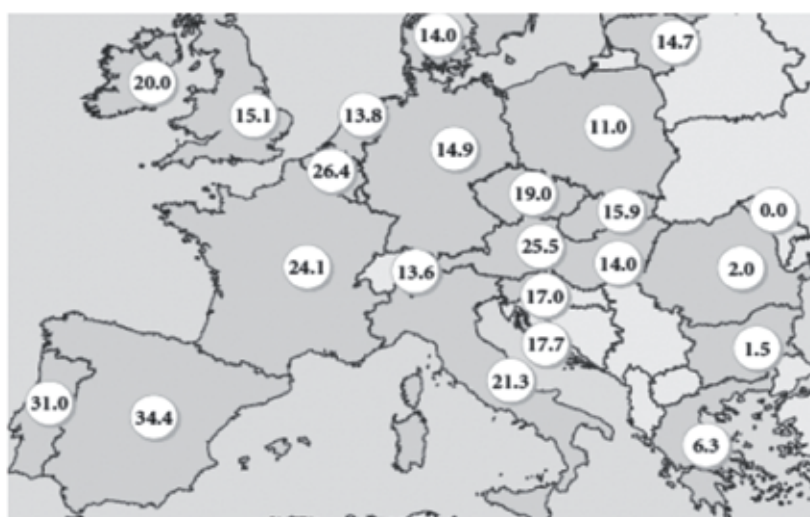
of deceased donors pmp in 2009 was 34.4, in Portugal was 31 whereas in countries like Greece the annual rate of deceased donors pmp was 6.3 (Figure 3). An high percentage of the countries that participated in the EC survey [1, 3], have binding legislation in place on general ethical principles for the protection of the donor, such as anonymity, confidentiality and remuneration. The last is of major concern for all the countries on a global level resulting in measures for preventing organ trade or trafficking [7, 14-16]. The cost of transplantation has generally fallen over time, while survival and quality of life have improved. This indicates that the cost-effectiveness of transplantation has also improved over this period [7, 12]. According to the World Transplant Registry (Table 3), the kidney and liver transplants are highest both in demand among the solid organs and in number of transplantations performed. Renal transplantation

TABLE 2

LEGAL SYSTEMS REGARDING CONSENT TO ORGAN DONATION (MODIFIED BY ROELS L ET AL, [7])		
COUNTRY	LEGAL PRINCIPLE	DATE OF LAW
Greece	Opting out (“soft”)	1999
Czech Republic	Opting out	2002
Portugal	Opting out	1993
Belgium	Opting out	1986 (amended in 2007)

FIGURE 3

DECEASED DONORS, ANNUAL RATE PER MILLION PEOPLE (MODIFIED BY MATESANZ R, [2])



appears to be both cost-effective and cost-saving compared to dialysis [17-19]. Common methodological issues include, but are not limited to, missing cost-categories, limited perspectives, reduced follow-up, and lack of sub-group analyses. More research is needed in all areas, using health economic theory and methods [5, 17, 20]. Several economic evaluations regarding the cost-effectiveness of renal transplantation (kidney transplantations - KTx), and reviews of such studies, have been performed [5, 12, 21-27] (Table 4a; Table 4b). Renal transplantation should thus be expanded to replace dialysis treatment, as this will both save resources in the health care sector and improve health outcomes for the patients. However, some of the studies also indicate that the cost-effectiveness ratio will differ between different population subgroups. A rather common assumption in earlier studies is that life expectancy without end-stage renal treatment is non-existent and hence that the alternative

for comparison to KTx carries no costs and no benefits. Many studies consider the costs and effects of renal treatment over the entirety of the patient's remaining life, but others consider them for only a certain number of years. This restricted follow-up time affects the cost-effectiveness ratio, and should therefore be avoided [6, 11, 20]. It is not always easy to determine the extent to which the different studies account for unsuccessful transplantations, and so the effect this might or might not have on the general conclusions cannot be further commented on [27-29]. It should be noted that not all of the studies of living donor transplantation take into account the costs and/or increased risk for the donor [17, 19]. It is difficult to attain the potential of Brain Death Diagnosis (DBD), since organ donation and procurement is a very delicate and complex process that is affected by many factors and can be easily interrupted at any time. Moreover, the whole process must take place in a very short

TABLE 3

LEGAL SYSTEMS REGARDING CONSENT TO ORGAN DONATION (MODIFIED BY ROELS I ET AL, [7])	
TRANSPLANTS	GLOBAL ESTIMATES OF SOLID ORGANS
Kidney	65 511
Liver	20 366
Heart	5 313
Lung	3 051
Pancreas	2 551
Total estimates of solid organs	90 000-95 000

TABLE 4a

ECONOMIC EVALUATION STUDIES ON KIDNEY TRANSPLANTATIONS (MODIFIED BY JARL J ET AL, [12])							
	COUNTRY	YEAR	N	TYPE OF STUDY	APPROACH	PERSPECTIVE	ALTERNATIVE
Kontodimopoulos & Niakas 2008	Greece	Not stated	874 for estimation of outcome	Survey / retrospective	Cost-utility	Not stated	Not stated (immediate death)
Quinn et al 2007	North America	Not stated	NA	Markov model	Cost-utility	Health care	Dialysis
Whiting et al 2004	Canada	Not stated	NA	Markov model	Cost-utility	Health care payer	Dialysis
Matas & Schnitzler 2003	USA	1995-1999	NA	Markov model	Cost-utility	Societal	Dialysis
Perovic & Jankovic 2009	Serbia	2008	150 (50 KTx)	Not stated	Cost-utility	Health care payer	Dialysis
Schweitzer et al 2007	USA	2002	NA	Markov model	Cost-utility	Not stated	NA
Cleemput et al 2004	Belgium	1999-2002	NA	Markov model	Cost-utility	Societal	Dialysis
Greiner et al 2001	Germany	1993-2004	1 149 (169/77 KTx)	Prospective	Cost-utility	Societal ?	Dialysis
Kaminota 2001	Japan	1995	26 233 (604 KTx)	Retrospective ?	Cost-utility	Health care payer ?	No treatment (dialysis)
Jassal et al 2003	NA	NA	NA	Markov model	Cost-utility	Health care payer	Dialysis
Kalò et al 2001	Hungary	1994	1 082 (242 KTx)	Retrospective	Cost-effectiveness	Health care payer	Dialysis

period of time, as organs with long ischaemic times are unsuitable for transplantation [14]. This compounds the weaknesses of the process itself, which could be slow down even more by ineffective procurement, by the absence of guidelines and criteria for considering DBD, by the lack of developed infrastructure, by the absence of competent quality and safety standards, by the lack of national quality programs and also by the ineffective or even in some countries lack of organ traceability systems for the reporting of serious adverse events and reactions. The organ transplantation urged several

EU countries to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to trafficking in human tissues and organs [14, 16, 30]. The principle of the prohibition of making financial gains with the human body is also essential in order not to jeopardise the donation system which must be the basis of the organ transplantation system [12, 31]. Yet ensuring that living donors are acting knowingly and voluntarily, even in the absence of financial incentives, is complex. Factors such as undue influence, family pressure and the

SYSTEMATIC REVIEWS AND META- AND POOLED ANALYSES

TABLE 4b

ECONOMIC EVALUATION STUDIES ON KIDNEY TRANSPLANTATIONS [MODIFIED BY JARL J ET AL, [12]]					
	OUTCOME	FOLLOW UP	DISCOUNTING	COST EFFECTIVENESS (US \$)	COMMENTS
Kontodimopoulos & Niakas 2008	QALY	Lifetime	5%	17 300/QALY(€ 11 981)	Clear focus on successful transplantation
Quinn et al 2007	QALY	25 years	Yes but rate not stated	Cost saving: 183 900 (CA \$ 192 093) per patient	Clear focus on successful transplantation. Age group analyses
Whiting et al 2004	QALY	20 years	5%	Cost saving: 15 400 (CA \$ 14 438) per patient	
Matas & Schnitzler 2003	QALY	20 years	5%	Cost saving: 124 400 (US \$ 94 579) per patient	Does not account for the increased risk for living donors
Perovic & Jankovic 2009	QALY	10 years	3% (cost only)	Cost saving: 148 100 (€ 16 385) per patient	
Schweitzer et al 2007	QALY	20 years	3%	Normal risk-kidney: 78 900/QALY (US \$ 60 000) Increased risk-kidney: 93 400/QALY (US \$ 71 000)	Transplantation of increased risk kidneys compared with normal kidneys, therefore no relevant alternative given
Cleemput et al 2004	QALY	Lifetime ?	3%	Adherence: cost saving: 79 900 (€ 48 717) per patient Non adherence: cost saving: 142 500 (€ 86 897) per patient ICER adherence vs. non adherence: 57 400 (€ 35 021)	Small sample, especially for non adherence
Greiner et al 2001	QALY	20 years	5%	KTx: 58 900/QALY (DM 38 300) Dialysis: 227 200/QALY (DM147 800)	Also estimates productivity losses
Kaminota 2001	DALY	Lifetime	3%	LDKTx: 17 600/DALY (¥ 2 322 000) DDKTx: 22 500/DALY (¥ 1 809 000) Dialysis: 91 800/DALY (¥ 9 456 000)	Utility weights from expert opinions. Estimations for different age groups
Jassal et al 2003	QALY	Lifetime	3%	60 yr: 90 300/QALY (US \$ 60 237) 65 yr: 101 600/QALY (US \$ 67 779) 70 yr: 118 900/QALY (US \$ 79 360) 75 yr: 149 200/QALY (US \$ 99 553) 80 yr: 206 800/QALY (US \$ 137 999) 85 yr: 346 500/QALY (US \$ 231 158)	Only includes patients in good form. Results are affected by length of time on the waiting list. KTx is not cost-saving for the elderly
Kalò et al 2001	Life years	3 years	0%	Cost saving: 29 300 (US \$ 18 290) per life-year gained	

difficulty of establishing a donor's actual physical and mental capacity to give voluntary consent have to be taken into account in establishing living donor programmes [16, 30, 32]. Despite the strong tradition that organs and tissues should be regarded as gifts, some members of the transplant community and policy-makers in several countries have expressed interest in allowing financial incentives for provision of human body material in the hope of increasing access to transplantation. Indeed, although payment is illegal in almost all countries, there are numerous reports that living "donors" of transplanted kidneys are remunerated directly or indirectly in many countries [8, 9, 31]. Moreover, in many countries education and training of intensive care nurses and doctors is not considered mandatory and this causes many problems since it could have immediate impact on organ donation [22, 33].

CONCLUSIONS

Organ transplantation has become a unique therapy able to save the life or increase the quality of life of patients with end-stage organ failure. It is a consolidated therapy which benefits almost 100 000 patients worldwide every year. Mainly because of the excellent results obtained with transplantation, demand for the therapy has gradually increased over the years, with a higher number of patients being placed on the waiting lists, while the number of donors and organs has not increased at the same rate. At present, it is not possible to meet the transplantation needs of the population, which are set to increase in the coming years. The degree of development of donation and transplantation activities varies greatly between countries, which results in unequal access to transplantation services throughout the world. For a variety of reasons, deceased donation programs have not

been developed or fully consolidated in many countries. It is evident that presumed consent laws have a significant impact on donation rates and positively affect the willingness of individuals to donate their own organs and those of a relative. As a result of shortage of organs for transplantation many patients will never be placed on the waiting list, and for those patients already on the waiting list the probability of deterioration or dying is high. Solving the shortage of organs for transplantation requires the development of an effective deceased donation program. The effectiveness of such a program mainly depends on legal, organizational and social aspects. While there is no substantial shortage of potential deceased organ donors, there is an inability to identify them and successfully activate and develop the process of deceased donation. Living donation should be seen as being complementary to deceased donation. However, it has been the main or the only source of transplantable organs in many countries. Recommendations and suggestions to increase the supply of organs must be weighed up carefully against the existing bioethical framework and culture in each country. It is crucial from a bioethical perspective that the criteria used to determine who receives a transplant are transparent, open to public debate and consistently applied. Otherwise, loss of confidence in transplantation would have a devastating impact on organ and tissue donation. Considering the limited organ supply, all necessary steps should be taken to make sure all available organs are properly safeguarded and used so as to maximize the benefit to patients. The establishment of an effective system making it possible to find people who can become donors after their death remains essential to increase the rate of donations. This system must ensure that the organs of people who wish to become donors will be always available.

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