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Consent Systems for Post Mortem Organ Donation in Europe

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INTRODUCTION

In the Netherlands, like in many other European countries, there is a considerable shortage of vital organs (hearts, kidneys etc.) for transplantation purposes. While living organ donation is of increasing importance as an alternative source for at least some organs (such as kidneys), the supply is still largely dependent on post mortem organ removal. This has resulted in mounting pressure on public authorities, hospitals and other parties involved to do everything to improve on cadaveric organ donation. However, continuing efforts in the field of general information of the public, education of professionals, and organisational measures at hospital level have had so far no or little effect on the number of transplantable organs. Therefore, the question has been raised whether the consent system for post mortal organ removal (that has been 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 of the Dutch population on organ donation, an analysis of the practice of organ retrieval in Dutch hospitals, as well as an international comparison of donation rates in order to identify the relative importance of the consent systems (as a factor influencing the availability of organs).¹ The study also included a comparative analysis of the consent systems in ten European countries. The aim of that part of the study was not only to delineate the similarities and differences between the various systems, but also to help in answering the question whether the change from an opt in to an opt out system could raise the number of cadaveric organ donations.

In this article, we present the main results of that comparative part of the study. After a brief introduction of different kinds of consent systems and the main principles and interests underlying them, we will describe the systems in force in ten European countries. Subsequently, we will discuss differences and similarities, with particular reference to the position of the next of kin of the deceased. In our final remarks we will address the question to what extent a change of consent system is likely to impact on the number of organs, also taking account of the results of the other parts of the larger research project.

CONSENT SYSTEMS IN GENERAL

There is general agreement that cadaveric organ retrieval is only allowed if some form of consent is available from the deceased or his relatives. This is also reflected in international guidelines and other documents. According to the Additional Protocol to the Biomedicine Convention concerning Transplantation of Organs and Tissues of Human Origin (Council of Europe, 2002), for instance, 'organs and tissues shall not be removed from the body of a deceased person unless consent or authorisation required by law has been obtained' and 'the removal shall not be carried out if the deceased person has objected to it' (Article 17).² 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 authorise organ removal after his death (in the form of an advance directive or donor card, or by filling in a form in order to record consent in a national registry). In the latter kind of

system, explicit consent is not required: it is sufficient that the deceased person has not objected during his life (according to national law); in that case consent is presumed. 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 characterised as opting out systems.

It is to be noted, that the dichotomy between ‘pure’ opting in and opting out systems represents an oversimplification that fails to recognise the nuances with which these systems function in practice. Usually, consent systems provide for involvement by relatives, either in the sense that they can act as a surrogate and give vicarious consent if the deceased person has not done so himself (opting in systems), or in the sense that they may object even if the deceased person has not registered an objection during his life (opting out systems).

An important operational aspect of consent systems (whether explicit or presumed) is the way the consent or objection is being recorded. A growing number of European countries have established national registries of donors (opting in systems) or non-donors (opting out systems) so that information on the willingness to donate is readily available and easily accessible for health professionals confronted with a potential donor in a hospital or elsewhere. In most cases, such registries have not completely replaced personal documents like donor cards, but they are becoming by and large the most important source of information on donor status. Usually consultation of that source is one of the first steps in the complex process that may result in organ removal post mortem. In order to have maximum information available on donor status and irrespective of the consent system in force, a register may record both consents and objections.

Whatever the system adopted under national law, it is obvious that it should meet basic standards of transparency and security, and provide legal certainty to donors and non-donors, to relatives and to the health professionals involved. As far as more substantive requirements are concerned, it is generally acknowledged that it should respect the principle of self determination of the potential donor. Although opting in systems are seen as doing more justice to that principle (at least if strictly applied, i.e. without interference of relatives), also opting out systems are considered acceptable in terms of self determination. Another value underlying the choice between different systems is that of solidarity with the vital needs of patients waiting for organ replacement. In this respect opting out systems are considered the better option, because – at least theoretically – they are likely to result in more donations. Finally, consent systems should take account of the special position of the next of kin. Apart from the fact that relatives may be in the best position to express the presumed will of the deceased, they are emotionally deeply involved. Their feelings deserve respect and it is hard to see how health care staff could put aside their eventual resistance against organ removal.

CONSENT SYSTEMS IN 10 EUROPEAN COUNTRIES

In our comparative analysis we included the consent systems of 10 countries, i.e. Austria, Belgium, France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland and the UK. We did not only study the legislation in force, but (on the basis of parliamentary records, official documents and medico-legal literature) also its background, important points of debate etc. Furthermore, we tried to collect at least some evidence on the way the systems operate in practice, mostly from written sources, but also by contacting transplantation coordinators. As to this last point, our aim was not so much to get a complete picture of every day practice (which would have been impossible) but rather to check whether the law was more or less applied as one might expect. In the following, we describe the main outlines of the adopted system per country.

AUSTRIA

The present law on organ transplantation dates back to 1982. It is not a separate act but consists of four provisions incorporated in the Krankenanstalten- und Kuranstaltengesetz. According to the law, Austria has a strict presumed consent system, with a national registry to record objections. Legally, relatives do not even have a right to be informed when organ removal is envisaged, let alone to veto it. However, there are strong indications that on this point the law is not applied in a strict sense.

According to several transplantation coordinators, when no objection of the deceased has been recorded, in most cases the next of kin are informed and asked whether they can agree with organ removal.³ One of the reasons given for this is the wish to maintain broad societal support and to avoid negative publicity. However, when consulting the relatives the absence of an objection of the deceased is taken as a point of departure.

BELGIUM

In 1986 a Law on the Removal and Transplantation of Organs was enacted. Organs may be removed after death unless the potential donor has made an objection (recorded in a national registry or expressed in another way), or unless the next of kin (i.e. partner or relatives in the first degree) show resistance. Objections of relatives do not prevail over the explicit consent of a donor (which can also be recorded in the registry). Although there is no legal duty to do so, if there is no record of the deceased's wishes usually relatives are informed of the fact that in principle he will be considered a donor.⁴ As to the question whether they are explicitly asked if they have objections, opinions and practices seem to diverge. Apparently, in some cases they are only informed about the envisaged organ retrieval. When the relatives are against organ donation, they have to take the initiative themselves to make their objections known.⁵ In other cases they are also informed about their right to veto and asked if they want to use this right. Only rarely are they asked for their consent.⁶

FRANCE

France is one of the first countries with legislation on organ donation. In 1976 the Loi Caillavet introduced a strict presumed consent system. In 1978 an additional decree came into force according to which, on behalf of the deceased, relatives could make a statement about his or her wish not to donate. In 1994, the existing law was modified by Loi 94-654 (one of the three so called bioethics laws), but the basic principles did not change. Objections are recorded in a national registry. If no objection has been recorded, the next of kin is asked whether the deceased person did object; they are not asked about their own feelings. The legislation has been evaluated in 1999.⁷ There are no signs that the actual practice is different from what is laid down in the law.

GERMANY

According to the Transplantation Act of 1997, Germany has an explicit consent system. Post mortem organ removal is allowed when the potential donor has expressed consent. One can do this by filling in an 'Organspendeausweis', an official document on which one can state consent or objection, or leave the decision to a particular person; there is no national registry. If there is not such a document, the relatives (designated by the law) are asked whether they know about any statement of the potential donor. If not, the responsible physician should ask their consent; however, they are required to decide on the basis of the presumed will of the deceased. The relatives in question should have had contact with him in the last two years before his death. We found no indications that the law is not applied. Of course it is difficult to know whether the next of kin really decide in the spirit of their dead relative, but the communication with them is based on this point of view.

ITALY

The requirements for organ removal post mortem are regulated by the law of 1 April 1999, Nr.91. That law revised the former law of 2 December 1975, Nr.644, according to which the removal was not allowed if either the deceased himself had objected, or his relatives did so after his death. The new law provides that every citizen is to be contacted in writing and informed that he can express consent or objection by filling in a form. One is also informed that if one does not record anything, consent will be presumed. The new law has not yet completely come into force. The new system can be regarded as a rather strict opting out or presumed consent system. However, at the end of 2003, transitional provisions were still in force that allow relatives to make an objection in writing in case an explicit will of the potential donor is lacking. Furthermore, there are indications that in practice relatives are often asked not to object against organ removal. It remains to be seen whether this long standing practice of involving the next of kin will really change after the new law has been fully implemented.

THE NETHERLANDS

In 1998 the Organ Donation Act came into force. At the age of 18 every citizen receives a donor form with several options: consent to organ removal or to removal of specific organs; refusal; leave the decision to relatives or to a specific person. When the form is sent back, the decision is recorded in a national registry (but one can also agree to donate through a personal document). If no decision has been recorded, the relatives designated by the law can give vicarious consent. In practice the law is implemented as intended. A recorded will is respected; if nothing has been registered, the next of kin are consulted. However, it is generally acknowledged that even if the deceased has consented, usually the relatives are still asked whether they agree.⁸

SPAIN

Together with France, Spain was one of the first countries with legislation on the subject. In 1979 Act Nr.30/1979 on removal and transplantation of organs was enacted, later followed by several orders and decrees, including the important Royal Decree of 30 December 1999 (Nr.2070/1999). The 1979 Act provides for a strict opting out system: removal of organs for therapeutical purposes is allowed when the deceased has not raised an objection. Decree 2070/1999 elaborates on this. To establish whether an objection has been made, several steps have to be taken (i.e. inspection of the medical file, search of personal belongings); also the relatives have to be consulted. However, since the introduction of the 1979 Act, the next of kin are in practice always asked whether they do agree with organ removal.⁹ According to a survey carried out in the 90s, about two thirds of the population was opposed to any modification of this practice.¹⁰

SWEDEN

Swedish legislation on the subject dates back to 1958, but has known several revisions since then (in 1975, but also in 1987 when a regime change to an opting in system took place). The present legal regime was enacted in 1996; in this law Sweden returns to its traditional preference – an opting out system. According to the act, every citizen can express consent or objections to post mortem organ removal, either through an official registry or by means of a personal donor card. If the will of the deceased person is not known, removal of organs is in principle allowed. However, the next of kin have a legal right to refuse, and they have to be informed in advance of the removal and their right to oppose. We found no evidence that actual practice was not in accordance with this legal regime.

SWITZERLAND

National legislation does not yet exist; several ‘cantons’ have enacted their own transplantation regulations. However, a bill on transplantation of organs, tissues and cells is being discussed in the Swiss parliament; it is expected to come into force by 2007.¹¹ This proposal is based on an opting in system. If the deceased has not consented to organ donation, his relatives can give consent. If there are no relatives or they cannot be contacted, removal is not allowed. In principle, the will of the deceased prevails over the will of the next of kin. The new law does not provide for a register; consent to donation is expressed on a personal donor card. In general, irrespective of cantonal law, an explicit consent system is practised in Switzerland, but not in its strictest form (i.e. next of kin play a decisive role, in particular if no consent is available of the deceased).¹²

UNITED KINGDOM

To post mortem removal of tissues the Human Tissue Act 1961 applies. It enables persons to give consent for removal and use of body parts after their death for several purposes, including therapeutical ones. The person or institution in possession of the body (this will often be a hospital if the potential donor died there, until it is claimed by the family or the coroner) has to allow use of body parts in accordance with the will of the deceased (unless it must be presumed that that will has changed). When his will is not known, the hospital may allow use of the body parts if it is established that the deceased person did not object against that use. In that case it has also to verify whether the partner or other relatives have objections. In 2003 UK Transplant issued the UK Hospital Policy for

Organ and Tissue Donation which provides practical guidance. Before organ removal, relatives are always consulted; the aim is to let them decide in conformity with the presumed will of the deceased.

On the whole, according to the letter of the law, the UK has an opting out system. In practice, the relatives are always asked to decide. For that reason, the system in force is often looked upon as an opting in system although strictly speaking it is not.

DISCUSSION

In all the countries discussed above there has been debate on the kind of consent system to be adopted, at least during the development of legislation on cadaveric organ donation. Essentially, the choice was between explicit and presumed consent of the donor. The first (opting in) is more in line with deeply rooted concepts about man's sovereignty over his body, also reflected by the right to self-determination. The second (opting out) does not deny personal autonomy, but tries to do more justice to moral obligations of solidarity with the severely ill. It is obvious that the latter system can only achieve its purpose (i.e. to yield more post mortem organs) if it is widely accepted by the health professions and by the public at large. However, in spite of these different perspectives, there is consensus between all countries that the explicit will of the individual – either a consent, or a refusal – needs to be respected, and therefore ought to prevail over the will of the next of kin.

In table 1 below we summarise the consent systems of the ten countries. Because the basis for defining their systems has been the known will of the deceased, we have indicated in the first place how that will can be known (i.e. by means of a national registry and/or an official donor card). In the second place, the preferred system (opting in or opting out) is indicated.

[TABLE 1]

If respect for the explicit will of the deceased is the basic principle in all systems, the question is of course how one deals with a situation in which no such will is known. Will the relatives then be involved? And if so, how and to what extent? Three possibilities can be distinguished: relatives are not involved; they are to give consent; they can make an objection. Table 2 summarises the role of relatives when an explicit decision of the deceased is lacking. Because their role in practice is often not the same as their role according to the letter of the law, we make a distinction between law and practice.

[TABLE 2]

It appears that relatives are involved in all countries, irrespective of the law in force. Even in Austria, where according to the law relatives have no role at all, apparently they are asked in most cases whether they can agree with organ removal. In addition to arguments of respect for the special position and feelings of the next of kin, dictated by custom and practice, involving them is usually also motivated by concern about negative publicity and loss of support for organ donation if one overrules their resistance. Taking into account the practice in all the countries reviewed, we can conclude that there is factual consensus on the need to involve them if an explicit will of the deceased is lacking. One further point should be noticed. If in an opting out system relatives are asked for consent, it becomes hard to distinguish it from an opting in system; the two systems come very close then. If one looks at the position of the next of kin only, the systems in Spain and the UK (and even that in Austria) may be considered opting in systems; in fact – as we have seen – the prevailing system in the UK is often perceived as such.

Apart from the fact that when there is no recorded decision of the deceased the involvement of relatives can vary in terms of giving consent or making objections, the description of law and practice in the countries surveyed show that also the way relatives are being consulted may differ. In Belgium, for instance, the next of kin are informed about the envisaged removal of organs, but they are not always explicitly asked whether they do object. Furthermore, in some other countries relatives are

requested to decide in accordance with the presumed will of the deceased; this approach can be found both in countries with an opting in system (Germany) and in countries with an opting out system (France and Spain). In the UK, a similar approach has been laid down in the Hospital Policy for Organ and Tissue Donation. Finally, in some countries (Netherlands; Switzerland) relatives are allowed full discretion to make their own decision. We did (and could not) ascertain to what extent these different approaches are actually followed and how they are carried out in daily practice. Presumably, the personal style, skills and experience of the health care staff involved play an important role. It is quite possible, therefore, that in every day reality the formal difference between asking for consent and asking for objections is (further) reduced.

FINAL REMARKS

It is often argued that opting out systems are likely to result in a higher supply of post mortem organs than opting in systems. Theoretically, this may certainly be the case, but what about actual practice?

On the basis of the above descriptions alone, one cannot definitely answer that question. What can be concluded from our discussion, however, is that in reality the different systems are much more similar than suggested by the explicit/ presumed consent distinction. In particular the predominant role of relatives in case no decision of the deceased has been recorded (and that is the most frequent situation in all countries) increases the potential of the strict opting in system, and reduces that of the strict opting out system, making it dependent on specific conditions (such as the existence of a strong commitment to donation among the population) whether indeed an opting out system will be more successful.¹³ In the meantime, our research also demonstrates that law and practice do not always correspond. To get a complete picture of the practice in the different countries, more extensive research would be required.

Another point, also often touched upon in the international literature, is the importance of other factors influencing the availability of organs. Road accident rates, for instance, are also a relevant factor; the same holds for failure by medical staff to identify potential donors or to take the necessary steps for organ procurement, which in many cases accounts for the loss of organs.¹⁴ In our overall research project we observed differences between the ten countries in the number of post mortem organ donations per million inhabitants but we could not relate that variation to differences between opting in and opting out systems. There are countries with an opting out system with a lower rate than countries that have adopted an opting in approach. Obviously, other factors play a role, and presumably a more decisive one. This means that a system change is likely to have only a limited effect, if any effect at all.

Under some local circumstances (e.g. the commitment of the population to organ donation is overestimated; the adoption of an opting out system is perceived as coercive; the changes are too complicated or are poorly communicated) such a change may even lead to less donations. As to the attitude of the population, in our research in the Netherlands we found that a large majority of the population continues to support the involvement of relatives of the deceased. We also observed that if an opting out system would be introduced, much more persons were likely to register an objection than under the present opting in system. On the whole, therefore, we recommended that the Dutch system should not be changed, the more so because we found that there were still other measures within the existing system (for example recontacting of persons that did not register so far; information campaigns directed at the position of relatives; organisational measures at hospital level) that could increase the supply of post mortem organs.

NOTES:

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1. R. Friele, J. Gevers a.o., Tweede Evaluatie van de Wet op de orgaandonatie, ZON/MW, The Hague 2004.
2. See also the WHO Guiding Principles on Human Organ Transplantation (Geneva 1990): 'Organs may be removed from the bodies of deceased persons for the purpose of transplantation if (a) any consents required by law are obtained, and (b) there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person's lifetime.'
3. See also C.-L. Fischer-Fröhlich, 'Die Situation der Organtransplantation in der Bundesrepublik Deutschland und im europäischen Ausland aus medizinischer Sicht – eine Bestandsaufnahme', in: E. Baacke, G. Ruprecht (ed.), *Organentnahme und Transplantation im Spannungsfeld zwischen Ethik und Gesetz*, Stuttgart: Landeszentrale für Politische Bildung Baden-Württemberg 1997, p. 7-28.
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6. Michielsens 1996, p. 663-665.
7. Claeys M.P., Huriet C., *Rapport sur l'application de la loi no. 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal*, Paris: l'Office parlementaire d'évaluation des choix scientifiques et technologiques 1999.
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11. Schweizerischen Bundesrates, *Botschaft zum Bundesgesetz über die Transplantationen von Organen, Geweben und Zellen (Transplantationsgesetz) vom 12. September 2001*.
12. Schweizerischen Bundesrates, *Botschaft zum Bundesgesetz über die Transplantationen von Organen, Geweben und Zellen (Transplantationsgesetz) vom 12. September 2001*, p. 79.
13. See for similar observations several other authors on this subject, such as R. Matesanz, 'Cadaveric organ donation: comparison of legislation in various countries in Europe', *Nephrol. Dial. Transplant* (13) 1998 ('Social reality interferes with the wish to change reality by an act of law. At the very best everything returns to the status quo.') and G. Palea, D. Pegg, 'The ethics of donation: changes are necessary and soon', *The Lancet* (362) 2003, p. 932 ('... as long as the agreement of relatives is required, an opt-out system would probably have a small overall effect on donation').
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