

Procuring organs for transplantation

A European perspective

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Background: The shortage of organs for transplant in Europe has been considerable for many years. A number of different policies have been implemented in an attempt to address this problem. These have had varying degrees of success from country to country. **Methods:** This article provides an up-to-date review of organ procurement policies throughout Europe. Alternative and in some cases controversial organ procurement programmes are also considered to establish whether the increasing demand for organs can be met elsewhere. **Results:** Transplant waiting lists are the greatest by far for those patients waiting for a kidney replacement. Norway has best managed to address this need through adopting a positive policy choice towards live donation whilst still maintaining an active cadaveric donation policy. **Conclusion:** With the lowering of both physical and social barriers in Europe, there has been a recent shift towards co-operation between some European countries in promoting transplant activity. This ensures that if an organ becomes available in one country and has no suitable recipient, then it can be used elsewhere. The future may show an increasing trend towards this level of European cooperation in order to make transplant activity more efficient.

Key words: cooperation, donation, Europe, organs, policy, transplant

The purpose of this paper is to provide an up-to-date review of the current status of frequently changing public policies in Europe for the procurement of donor organs for transplantation. This paper consists of two main parts: firstly, an outline of European transplant activity and, secondly, an assessment of the different public policies pertaining to transplant activity. This will also include a discussion of the implications for introducing new and possibly controversial policies related to procuring increased numbers of organs.

In Europe, there is currently a crisis over the supply of organs for transplant; this supply is increasingly unable to meet the growing demand.^{1,2} The most recent and worrying statistics show that throughout the European region (this includes the following transplant-active countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, The Netherlands, Hungary, Italy, Norway, Portugal, Spain, Sweden, Switzerland and the UK) the numbers waiting for a kidney transplant had reached almost 40,000 by the end of 1994, with the gap between those waiting and those receiving a transplant growing wider.² This pattern is also mirrored for other major organs such as the heart, lung and liver in the European region as well as worldwide. For organs such as the heart, pancreas, liver and lung, successful donation is

only possible from dead donors (cadaveric donation). This is not the case for the kidney, however, where it is possible for a person to donate a kidney while alive and still lead an active and healthy life with the one remaining kidney. Thus, there are two major sources of organ procurement for the kidney, either cadaveric or living donors.

This article will focus upon the kidney since this is where the problem is greatest because of the increasing number of patients now recognized as requiring and likely to benefit from renal replacement therapy. Since kidney transplantation is the longest established and most widely practised of the transplant operations, international data are the most complete and reliably available.¹ Unfortunately, equivalent data is not widely available for other organs. It may be noted, however, that much of the discussion related to procuring kidneys from cadaveric donors can be applied to the other major organs and these links will be highlighted where appropriate.

EUROPEAN TRANSPLANT ACTIVITY

This section deals with cadaveric and live kidney transplantation rates in Europe for the year ending 1994. A note of caution should be added at this point about the interpretation of results as these rates will depend on the particular circumstances prevailing during a particular year. The figures presented, however, do highlight trends and patterns of transplant activity. Countries ranked by their 1994 cadaveric kidney transplantation rate are shown in *figure 1*. Austria, Spain, Belgium, Finland and Portugal show markedly higher transplantation rates than

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the other European countries ranging from 34.9 per million population (pmp) for Portugal to 42.2 pmp for Austria. There then follows a cluster of countries which have broadly similar transplantation rates ranging from 23.4 pmp for Hungary to 30.2 pmp in Switzerland. The remaining countries, Italy, Luxembourg and Greece in particular, have much lower rates of cadaveric transplantation. This can be partly explained by their more recent involvement with transplant technology.

Live donation also varies significantly throughout Europe, as shown in figure 2, but, with the exception of Finland, the Scandinavian countries appear to have been particularly successful in procuring kidneys. Norway has by far the highest rate, with 17.7 pmp. Others, including the five leading cadaveric transplant countries, undertake relatively few. Portugal, for example, conducts no live transplants at all. A pattern emerges here in that the more successful a country appears to be at procuring cadaver organs the less likely it is to undertake live transplants and vice versa.

Upon analysing the total number of kidney transplants undertaken and the proportion of this total made up by live transplants, one can see that Norway has the greatest with 44.5 pmp (figure 3). Switzerland performs a large number of cadaveric transplants yet also has a modest live donor programme, both contributing to the high total number of grafts. Many of the countries low in the league table, with the exception of Greece, use few live donations. However, Austria and

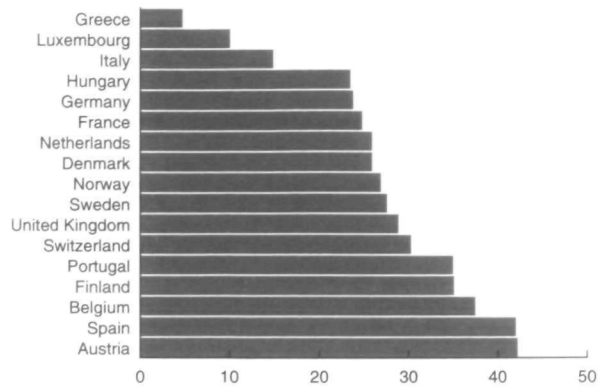


Figure 1 Cadaveric kidney transplantation rates (pmp) in Europe's leading transplant countries, 1994
Source: Council of Europe Transplant Newsletter, March 1996

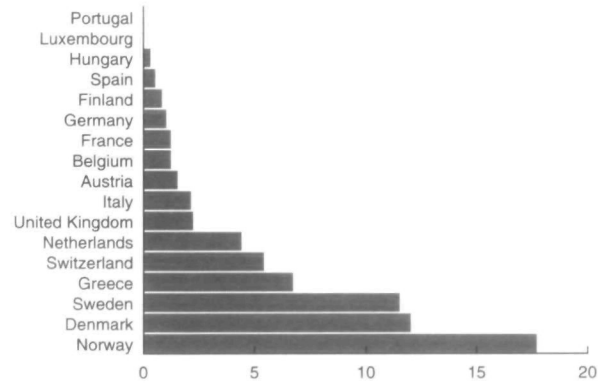


Figure 2 Live kidney transplantation rates (pmp) in Europe's leading transplant countries, 1994
Source: Council of Europe Transplant Newsletter, March 1996

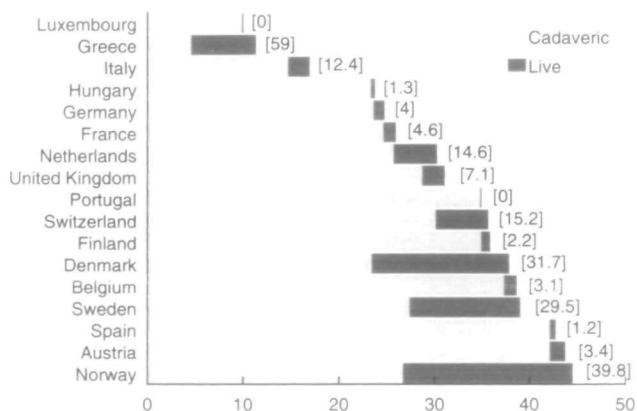


Figure 3 Total kidney transplantation rates (cadaveric plus live) (pmp) and the proportion of live transplants, 1994
Source: Council of Europe Transplant Newsletter, 1996
[%]: Live transplants as a proportion of total

Spain, two of the three countries achieving the highest number of grafts, carry out few live donations.

The data presented above highlight the current status of transplant activity in the major transplant-active countries of Europe. This paper now goes on to investigate the various public policies in these countries relating to organ procurement to establish whether there are successful policies operating in certain countries which may be worth considering for those countries who as yet have been relatively unsuccessful in procuring organs.

It must be stressed that organ procurement policies are not the sole influence on transplantation rates. Other influential factors include death rates from relevant causes, the demographic and physical characteristics of a country, level of health care funding and cultural factors.¹ However, policies can at least be implemented and adapted by the relevant authorities depending on the transplant situation.

ORGAN PROCUREMENT PROGRAMMES IN EUROPE

Cadaveric donation

The countries of Europe can be categorized according to their adoption of one of two types of organ procurement programme. These might be broadly termed as the 'opting-in' and 'presumed consent/opting-out' legal systems. Opting-in relies upon voluntarism and is mainly operated with the use of donor cards or donor registers. Opting-out, on the other hand, is a scheme where consent to organ donation is presumed unless a person has expressly refused permission by signing on an opting-out register.³ Fundamentally, in an opting-in scheme what individuals register is a wish to donate, whilst in an opting-out scheme what is registered is a refusal to participate.

Table 1 Cadaveric kidney transplantation rates (pmp) in Europe's leading transplant countries, 1994

	pmp	Opting-out legislation
Austria	42.2	Yes
Spain	42.0	Yes
Belgium	37.4	Yes
Finland	35.0	Yes
Portugal ^a	43.9	Yes
Switzerland	30.2	
United Kingdom	28.8	
Sweden	27.5	
Norway	26.8	Yes
Denmark	25.8	
The Netherlands	25.8	
France	24.7	Yes
Germany	23.7	
Hungary	23.4	
Italy	14.8	
Luxembourg	10.0	
Greece	4.6	

a: Opting-out legislation in Portugal was introduced in 1994

Examining the ranking of the European countries according to their cadaveric kidney transplantation rates and the legal system in operation (*table 1*) shows that presumed consent may indeed be an important factor in increasing donation rates. The leading five countries each has some form of presumed consent legislation. Analysis of the effect of introducing an opting-out law has been considered previously and it has been demonstrated that it has a positive impact on the number of available organs in Austria, Belgium, and Singapore.^{1,4}

The two public policies, however, are fundamentally based on different ethical and social values. Any legislation veering towards one or the other would need to deal with these issues both at the government and public level.

Opting-in

The opting-in system is in use in many countries and is facilitated by people carrying a donor card or signing on a organ donor register. For this system to have a direct impact on procurement rates either a donor card must be found on the body of the deceased at or shortly after the time of death or the deceased person's name should be on the donor register. Even so, in the UK and in some other European countries, it is usual to obtain the consent of the next-of-kin in addition, if this can be done in time for the organs to be viable.

As an indirect way of raising public awareness the impact of the card and register cannot be overestimated.^{1,3} In several countries, national publicity campaigns have been used to increase the uptake of donor cards and ultimately increase donation rates. One example of their potential influence can be seen in the 42% increase in the number of kidney donations in Britain in 1984 which coincided with a 6 month campaign conducted by the Department of Health and Social Security using television and newspaper advertising to describe the donor card system.⁵ Such publicity can affect card carrying directly and can also have indirect effects on donation by initiating debate and increasing awareness.³

Efforts such as these are highly commendable but have done little to address the underlying problem which is to achieve card carrying or signing on the donor register amongst those members of the public whose families would otherwise have refused consent.¹ This can only be tackled through concerted education campaigns, using various forms of media to highlight the benefits of transplantation and appeal to the public's sense of altruism.⁶

Presumed consent

A presumed consent law presumes that an individual has consented to organ donation at the time of death unless there is contrary documentary evidence or, in some countries, objections by the family.¹ Assuming that the commitment of society were strong towards donation and that the public trusted the concept and application of brain death, this system should theoretically reduce the donor shortage drastically. The positive impact on transplantation rates is visible in *table 1*, but there are moral issues to consider in implementing such a policy.

Presumed consent schemes have been introduced into many European countries (Austria, Belgium, Finland, France, Italy, Norway, Spain, and Sweden). The arguments in favour of presumed consent are based on the presumption that there will be a marked reduction in transplant waiting lists. It is argued that such a statute could be introduced whilst giving people the opportunity to opt-out on religious or moral grounds.⁷ This is the case in Singapore where a presumed consent system is in operation but excludes all Muslim citizens as they prefer to exercise the right of opting-in.⁴

The arguments against presumed consent are that only the educated and more advantaged groups in society are able to exercise informed choice and act autonomously in such a scheme and the situation can arise where the poor and uneducated would not have the same autonomy due to lack of knowledge. We could also reach the stage where patients close to death would be looked upon solely as a source of organs.⁷

Live donation

Live donation legislation has been introduced throughout Europe and implemented with varying degrees of success. The principal source of live donations is from those who are both genetically similar and related to the recipient but sometimes donors are those who are not genetically similar but are related (spouses) and, in special circumstances, donors who are genetically similar but unrelated to the recipient. Strict regulations have been implemented to control the latter type of donation to reduce the possibility of non-voluntary donors.

It is evident from the figures on European transplant activity that Norway has pursued a live donation policy more actively than its counterparts in Europe. The main reason for this is its low population density: there are organizational implications for transplantation activity attached to a small population living in a large country. Norway is constrained by the fact that it has only one transplant centre in Oslo. This has had a major influence on the low rate of cadaveric transplant activity due to the large distances between the donor hospitals and the transplant centre. Thus, the live donor alternative is a much more appealing proposition and is pro-actively pursued as a procurement option.

The Norwegian programme involves exploring the possibility of live donation as soon as the decision for transplant is taken. Family members are assessed for suitability and the possibility of live donation is discussed where transplantation is feasible. The act of donation must be demonstrably voluntary and, if there appears to be any signs of coercion or feelings of obligation, the physician will declare the potential donor medically ineligible for donation thus relieving the family member of any responsibility for making such a decision. This also serves to dispel any doubts or suspicion on the part of other family members of the donor's willingness to take part.⁸

For those patients waiting for a kidney transplant, the time and financial and emotional costs of travelling to and from the dialysis centre two or three times a week are

extremely heavy.^{6,8} This is true for all patients regardless of their country of residence. Taking a pro-active approach to live donation has been shown to be an important determinant in increasing procurement rates since the number of live transplants performed in Finland, another country with a low population density but a less-organized approach to live donation, is far fewer.¹

As is the case with all other forms of transplant policy, live donation raises a number of ethical concerns. Firstly, there is the issue that live donation is a procedure that may not be in the medical interests of the donor.⁹ As such, it is a practice which runs counter to the medical profession's code of ethics. However, what needs to be balanced are, on the one hand, the medical benefits to the recipient and the emotional benefit to the donor, who is in most cases the recipient's close relative and, on the other, the minimal but nevertheless real risk to the donor of invasive surgery.¹⁰

A final concern is that there may be financial inducements offered to persuade people to donate organs. This relates more specifically to unrelated donors. Measures have been taken to outlaw this procedure in Europe and throughout the rest of the world by introducing statutes prohibiting trading in human organs such as the Human Organ Transplants Act (1989) in the UK.⁷ However, this practice is very difficult to monitor, particularly in the case of intrafamily exploitation.

Future alternatives

Elective ventilation

Traditionally, the intensive care unit (ICU) has been the main source for organ donation as the vast majority of donors are those who have sustained some form of fatal head injury, normally as a result of a road accident or those patients who have suffered a cerebrovascular accident (stroke). However, there is a supply of potential organ donors in general wards which has been previously overlooked: patients at risk of suffering a cerebrovascular accident while on the ward. If these patients were identified and subsequently transferred to the ICU, they could be artificially ventilated to preserve the organs until brainstem death can be established.

Clearly there are ethical concerns with such an initiative. Elective ventilation is not in the interests of the patient but of the organ recipient. For such practice to conform to legal statutes, patient consent would be required yet this is not possible as the donor would be in coma before ventilation was even considered.¹ A recent report by the British Transplant Society has recommended legislation to overcome these concerns.^{11,12}

A protocol for electively ventilating patients has been developed in Exeter, UK. This has proved to be highly successful, inasmuch as initial predictions show an increase in donors of 50%.¹³ Large-scale clinical trials are planned in order to evaluate the wider potential of elective ventilation effectively. A rigorous ethical protocol that addresses the above issues will need to be in place before such an initiative could commence.

Non-heart-beating donors

As stated earlier, the vast majority of cadaveric donors die as a result of cerebrovascular accidents and fatal head injuries, where brain death has been established. With advances in medical technology, another potential source of organ donors has been identified in those patients who have suffered a fatal cardiac arrest and where brain death is inevitable and irreversible. It is possible to harvest the kidneys of patients in these circumstances.¹⁴

This procedure would operate if cardiac arrest has occurred. The kidneys would then be protected by cold perfusion until family consent for organ donation could be established. Cold perfusion involves inserting an irrigation tube into the non-heart beating donor.¹⁴ Pilot clinical trials of this procedure have been undertaken under the strict supervision of medical authorities and the consent of relatives in The Netherlands and Leicester, UK. The initial results are very promising showing an increase in the number of kidney transplants by 21% over a nine year period in The Netherlands and 38% over a one year period in Leicester.¹⁴⁻¹⁶

Even if clinical trials are evaluated successfully, an ethical point of concern remains with this procedure. Performing invasive surgery in order to insert the irrigation tube into the dying patient before consent has been established can be viewed as an act undertaken solely for the purpose of procuring organs which is not in the interests of the patient.¹ This could lead to further ethical and legal problems if consent is refused and the patient's relatives react adversely towards the surgery.

Xenotransplantation

The most recent and radical solution to reduce the scarcity in organs is the development of xenotransplantation, the use of animal organs for transplantation into humans. Research is being carried out in Cambridge, UK, where it is hoped the strong human immunological response to foreign tissue can be overcome by using organs from genetically altered pigs. The idea is to trick the human immunological response into thinking the pig's heart is its own.¹⁷

Clearly, xenotransplantation is controversial and raises a number of concerns. The risk of a variety of diseases spreading into humans coupled with the ethical problems of using animal organs suggests that further consideration should be given to alternative organ procurement programmes.¹⁸ This is the stance recently adopted by the Department of Health's Advisory Group on the Ethics of Xenotransplantation in the UK.¹⁹

DISCUSSION

A review of transplant activity in Europe and relevant public policies shows that all methods of organ procurement entail both organizational and ethical problems. For example, pursuing a live donation programme more vigorously than cadaveric donation has obvious repercussions for the types of organs procured. The number of kidneys obtained will clearly be much greater but there will be a correspondingly lower number of hearts, lungs,

livers and pancreases procured. If demand for these organs increases, then countries may be forced to adopt a more aggressive approach towards cadaveric donation.

One cannot overlook, however, the extent to which the success of organ procurement programmes in some countries, particularly Norway, depends on an active live donation policy. The main proviso is that such an initiative requires close monitoring to ensure that the donor is acting voluntarily and that there is no sign of coercion or exploitation. Given the increased recognition that end-stage renal failure in older patients and diabetics can be effectively treated, kidneys are currently the organ in greatest demand.²⁰ Live donation offers the best possible hope of procuring a suitable kidney donor quickly. A positive policy choice, as implemented in Norway, is a policy to which other European countries should give serious consideration. Simply enacting legislation to make live donation permissible is not enough.

Ideally, each country should have an active cadaveric donation programme running in parallel with live donation arrangements. The problem lies in identifying the most suitable cadaveric programme to implement since none is without its limitations.³ Donor card holders may not be identified either because the card is not found or, in some cases, is not looked for. The family of the deceased may conceal the existence of the card and the operation of a veto by relatives may frustrate a genuine desire on the part of the deceased to become a donor. Similar problems may occur in identifying patients who are on the donor register as quick and accurate access to the register is required by all hospitals involved with the transplantation.³

Obtaining consent from the patient's relatives is an integral part of the process of voluntary donation. However, research has shown that many medical staff find it very difficult to make such an approach.²¹ There is no doubt that the most important determinant of the frequency of organ donation is the willingness of the medical and nursing staff caring for potential donors to initiate this process and to undertake the considerable extra work it entails.²² Training programmes for medical staff that address the highly sensitive issue of dealing with bereaved relatives and making a request for organs are essential.²³ The opting-out or presumed consent policy operates in the five countries with the highest cadaveric transplant rates. The danger is that a presumed consent protocol may run counter to an individual's and/or relatives' beliefs yet be in operation before this becomes known. This is a risk which is particularly likely to affect those who are least well-equipped to make an informed choice about opting-out.^{3,7}

Future interventions for procuring organs such as elective ventilation and xenotransplantation also raise ethical concerns. There is no doubt that if appropriate measures were taken the supply of organs through existing programmes could be markedly increased. Xenotransplantation in Europe or any other part of the world for that matter should not go ahead until the existing national organ procurement programmes are reviewed and the

possibility of introducing other human organ procurement programmes which are used currently in some other countries is explored.¹⁸

CONCLUSION

The way forward seems clear; adopting a positive approach towards live donation whilst maintaining an active cadaveric programme. No matter which type of organ procurement policy is implemented, measures need to be taken to attract more donors. This may be achieved through sustained awareness-raising and education campaigns for both the public and health professionals.^{1,3} The benefits of and procedures involved in organ donation and transplantation are key messages to deliver. If there was a move to change procurement arrangements in some countries, then new laws and regulations would be required. These in turn would require mass information campaigns to ensure they were accepted by the general public and enacted by politicians.

The success of such initiatives would see a marked increase in the number of transplants performed and thereby a reduction in transplant waiting lists. Given that the cost of a transplant is lower than maintaining a patient on dialysis, there are clear long-term economic benefits for national health services in promoting transplantation activity, with millions of pounds saved each year. As a general rule, the cost of a successful transplant plus one year of post-operative therapy amounts to less than the cost of one year of the cheapest form of chronic dialysis. After the first year of post-operative therapy, the costs are much lower than annual dialysis.²⁴

With the desperate shortage of organs clearly apparent throughout many European countries there has been a shift towards cooperation between countries in order to attempt to alleviate the problem. Eurotransplant and Scandiatransplant are examples of such organizations where countries are jointly promoting and organizing transplant activity. (Eurotransplant covers Austria, Belgium, Germany, Luxembourg, and The Netherlands, while Scandiatransplant covers Denmark, Finland, Norway and Sweden). This ensures that organs which have become available in one country but have no suitable recipient can be used elsewhere. Thus, resources are saved and transplant activity is becoming increasingly efficient. It is hoped that other countries will follow this initiative and form trans-European health policy alliances.

BIOGRAPHICAL NOTE

The author is an active researcher and writer of policy analysis in the area of organ donation and transplantation. He was Project Director of a study (supported with a grant from the King's Fund) exploring the knowledge of and attitudes towards organ donation and transplantation among the Asian communities which has recently been completed.

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