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Comparative report on transplantation and relevant ethical problems in five European countries, and some reflections on Japan

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Abstract Comparison of transplantation medicine in Sweden, Denmark, Germany, Spain and Portugal reveals many and important differences with respect to frequency of transplantations, frequency of life donations, legal regulations and influence of the family on organ donation. The differences observed are at least partly related to cultural and value differences between the various countries, but many questions need to be studied systematically and in more detail before useful conclusions can be drawn. One study would have to address the problem of how differences in the family influence on organ donation can be explained. Another question needing further clarification concerns the exact meaning of “medical decision” and “medical criteria” because these terms, on which access to- and selection from the waiting list largely depends, are equivocally defined and seem to differ according to different traditions. Open questions also arise with respect to the influence of “closeness or distance” on medical decision making. The findings indicate that it would be premature to propose common guidelines to be observed within

Europe as long as the above mentioned and some further questions have not been systematically studied and thoroughly analyzed.

Key words Organ transplantation · Brain death · Allocation · Ethics · Cultural differences

Introduction

The research project on priority setting in health care, “Priorities and Resource Allocation in Health Care –

A Comparative Study of some European Countries”, compared detailed reports on the health care systems in Sweden, Denmark, Germany, Spain and Portugal. From this study it soon became evident that there are

more pronounced differences between these systems than assumed from the literature. At least some of the differences seem to be related to different cultural traditions and value assumptions. Since every health care system is a composite determined by a variety of factors, the influence of cultural and value differences can best be elucidated by selecting one particular aspect of the system for a more detailed study and comparison. For such a study we have chosen transplantation medicine.

The decision to select transplantation medicine was prompted for several reasons: 1. A comparison between countries is facilitated by the fact that in transplantation medicine, in spite of differently structured health care systems, at least two factors are identical in all five countries, namely the scarcity of organs available for transplantation, and the resulting waiting lists, which require the introduction of rules for allocation and thus the setting of priorities. 2. Organ allocation is of particular importance because it may imply decisions between life and death. 3. The procurement of organs entails decisions on anthropologically deeply rooted questions such as the nature of death and the perception of the human body. 4. Problems of personal identity may occur for the bearer of an implanted organ, particularly a heart.

In order to ascertain whether and, if so, what cultural traditions and value assumptions influence the decisions and priorities in transplantation medicine, it is sufficient to restrict the comparative study to the most frequently transplanted organs, i.e. kidney, liver, and heart. Following a brief introduction to the legal and organizational structure of transplantation medicine in the five European countries, this paper will concentrate on questions concerning the anthropological and ethical problems of organ procurement and allocation. In order to better illustrate the importance of cultural traditions and value assumptions for the appraisal of these problems, some reflections on transplantation medicine in an industrialized country with a highly developed system of health care, but belonging to an entirely different cultural sphere, i.e. Japan, will be included.

The Systems

In Sweden there are transplantation centers in 4 major university hospitals. These centers are run by the local county councils and supervised by the state (National Board of Health and Welfare). In Denmark there are 4 centers for kidney transplantations, 1 center for liver and 2 centers for heart transplantations. The establishment of transplantation centers is regulated by the law on the central regulation of the health care system. In Germany, 42 units are recognized as kidney transplantation centers, 25 units as liver- and 30 units as heart transplantation centers. Most, but not all of these centers, are

in university hospitals. Transplantation centers have to be licensed according to a procedure set out in the Code of Social Law. In Spain, 33 centers perform kidney and liver transplantations, and 12 centers carry out heart transplantations. These centers have to be licensed by the public authorities, and transplantations are only performed within the public health system. In Portugal 7 centers perform kidney transplantations, 4 centers liver- and 3 centers heart transplantations. The centers have to be licensed by the Ministry of Health.

Résumé

In all five European countries taking part in the study, the accreditation of transplant centers is regulated by the state. In those countries, where apart from a public-also a private sector of the health system exists, patients belonging to both systems are on the same waiting list so that equal access to transplantation is guaranteed.

Frequency of transplantations

Between the five countries there are great differences in the frequency of solid organ transplantations. As shown in Table 1, these differences are particularly striking with respect to kidney transplantations from living donors, where the highest frequency (Sweden with 13.8 p.m.p.) is more than 27 times higher than the lowest (Spain with 0.5 p.m.p.) There may be many and various reasons for these differences, and some may be related to different regulations for the procurement of organs, which in turn may be due to different cultural traditions and value assumptions. Therefore the procedures for organ procurement will be analyzed and compared in greater detail.

Procurement of organs

Three questions are critical for the procurement of organs: 1. What are the preconditions for organ removal? 2. Is the diagnosis of death by using brain related criteria accepted as death of the person? 3. What is the position

Table 1 Annual rate of transplants – 1997 per million population

	Sweden	Denmark	Germany	Spain	Portugal
Kidney					
cadaveric	23.9	21.7	22.8	46.4	38.2
living	13.8	8.6	3.5	0.5	0.6
Liver	10.3	7.4	9.3	20.0	14.3
Heart	4.0	6.1	7.0	8.0	0.7

Figures from: Transplant Newsletter vol. 3, Nr.1 (1998)

with respect to live donation? The answers to these questions and important differences are reflected in the legal regulations that apply in the five European countries investigated.

Access to cadaveric organs

In the five European countries, laws governing organ removal differ considerably, and the influence granted to the family of the diseased also varies. Three countries have a clear cut "opt out" system (Sweden, Spain, Portugal), two countries have an "opt in" system (Denmark, Germany). In Denmark, however, a previous decision of the deceased in favor of organ donation can be overridden by a veto of the next of kin. In Sweden and Germany, the next of kin have a right to decide if the wishes of the deceased are not known. Generally, the situation is complicated by the fact that while alive and healthy, many individuals are unwilling to bother making a decision on a potential organ donation. Therefore the introduction of donor or non-donor registers is of limited value only, particularly in an "opt out" system, which is intended to maximize the number of organs available for transplantation. In order to obtain reasoned and autonomous decisions of as many individuals as possible, great emphasis is placed in most countries on informing the public about the importance of transplantation medicine and on appealing to the sense of solidarity. In Germany, the statutory and private insurance funds are obliged by law to regularly inform their members and to advise them to declare their wishes in written form. In Spain, where everyone is considered a potential donor unless he or she has explicitly objected to organ donation, the consent of the family is usually needed to certify that the donor did not object.

Thus, in several European countries the family of the deceased has considerable influence on the decision to remove organs from the dead body. This influence of the family is even greater in Japan where a general reluctance to transplantation of cadaveric organs is prevalent, due to strong objections against mutilation of a dead body. In Japan the influence of the family is particularly great because important decisions, such as agreeing to organ donation, are usually made by the family as a group and not by the individual alone [2]. Usually, such decisions are not obtained through confrontational exchange of opinions but rather through a consensus of the persons concerned, and even individuals who personally would be willing to donate may request the additional consent of their families. Therefore, the new Japanese law on transplantation grants the family power of consent to organ donation on behalf of the deceased, and even if the deceased is registered as a potential organ donor, the family can override the decision and prevent organ removal.

Death due to total and irreversible loss of all brain functions

Although in all five countries total and irreversible loss of all brain function (including brain stem) is legally regarded as a prerequisite for the removal of an organ for transplantation, the diagnosis of death by using brain related criteria is not universally accepted as a valid criterion for the death of the person, and in several countries there have been fierce debates on this point in connection with the passing of transplantation laws.

When in 1987 a new law on criteria of death was introduced in Sweden, preceded in 1984 by the report of a governmental commission, fears were raised that by using brain related criteria, doctors would not be able to diagnose death with sufficient certainty. There was a lively debate in which the governmental commission took an active part. After the passing of the law the debate calmed down, and at present there seems to be very little opposition to the criteria of death as they are now accepted in Swedish law.

When in 1990 the diagnosis of death by using brain related criteria was about to be introduced in Denmark, there was also very lively public debate. Here, too, the argument was put forward that people who were artificially ventilated and had been diagnosed as having totally and irreversibly lost all brain functions were not dead but in an "irreversible state of dying" until the heart had irreversibly stopped beating. This view was also shared by a majority of the Danish Council on Ethics which had been set up in 1988. The Council advocated a solution which would have avoided the definition of death but would have made organ explantation legal when all brain function had irreversibly ceased. However, despite this intervention by the Danish Council on Ethics, the Danish Parliament passed a statute accepting irreversible loss of all brain function as a criterion of death of the person. Even now, there is still a fairly lively, albeit episodic, debate on the use of brain related criteria for the diagnosis of death, and some participants in the Danish debate want the law to be changed.

In Germany, which until 1997 had no special law on transplantation, the diagnosis of death by using brain related criteria was introduced already in 1968 by an official committee on "Reanimation and Transplantation" of the German Association of Surgeons (Deutsche Gesellschaft für Chirurgie). The diagnosis of complete and irreversible loss of all brain function soon became accepted by the majority of physicians, jurists, philosophers and theologians as a sign for the death of the person; and in general jurists agreed that although the definition of death had many important legal and social consequences, the criteria for the diagnosis of death were a matter of science and had to remain a domain of the medical profession. However, there was some fundamental and persistent opposition to accepting total and

irreversible loss of brain function as a criterion for the death of the person. The most prestigious and persuasive early critic was the philosopher Hans Jonas who, in 1974, published his objections in English and later in his German mother tongue. Jonas regards cessation of all brain function not as death of the person but as a transient stage in the process of dying – albeit as a stage from where on the process of dying has become irreversible. In his view, irreversible loss of brain function makes it mandatory to switch off all life sustaining machines and let the patient die peacefully. But he strongly objects to using what he regards as a dying person for organ procurement or any other purpose not directly benefiting that particular person. In his view, acceptance of total and irreversible loss of brain function as death of the person would amount to opening the doors to unwanted and inhuman instrumentalization of dying human beings. But the critics remained a small minority, and in 1990 the German Conference of Roman-Catholic Bishops and the Council of the Protestant Church in Germany issued a joint statement on organ transplantation that unequivocally accepted the criterion of complete cessation of all brain function as death of the person. However, the debate suddenly acquired an entirely new dimension when in 1992 a young woman who was pregnant in the 14th or 15th week suffered heavy brain damage in a car accident. In spite of intensive treatment, total and irreversible loss of brain function was diagnosed after 3 days and, accordingly, the death certificate was made out. However, in order to save the fetus, it was decided to continue ventilation and medical treatment of the dead body. But, after five weeks, some hours after ultrasound diagnosis had shown the fetus to be alive and well, spontaneous abortion occurred. The fetus was dead, and treatment of the mother was terminated. This case received enormous media coverage and aroused heated discussion. Was a patient whose pregnancy could be sustained for a period of five weeks after the brain had totally and irreversibly ceased to function really dead? Was it ethically justified to continue ventilation and treatment after the declaration of death, or would it have been better to switch off the machines and thereby also terminate the pregnancy? Was it right to create an ad hoc committee of doctors, including an expert in forensic medicine, to advise on how to proceed? Who else should have been asked to advise on the necessary decisions? These and many other questions suddenly brought the extent of the conflicting interests that have to be resolved by modern medicine to the attention of the general public. There were many heated public discussions, and also the opinions of experts were by no means unanimous. There can be no doubt that the emotions aroused by the “Erlangen case” are responsible, to a large extent, for the controversial and heated discussions that took place in the German Parliament, in the general public, and in the media when preparations for

a federal law on transplantation were initiated in 1994 [3]. These discussions continued until the Transplantation Act was passed in 1997, and the diagnosis of complete and irreversible loss of all brain function was accepted as diagnosis of death of the person. Since the passing of the new law, the discussion seems to have abated, but it can easily flare up again if a spectacular case is taken up by the media.

In Spain and Portugal, opposition to accepting diagnosis of irreversible loss of all brain functions as death of the person seems to have been less emotional and vociferous than in the northern countries.

The discussions concerning the diagnosis of irreversible loss of all brain functions as death of the person reveal the importance of different traditions in philosophical thinking as well as that of different historical experiences of the various countries in Europe. Thus, the particularly intense and drawn out discussion in Germany may reflect a continuing strong influence of certain holistic metaphysical conceptions in German philosophy and, in addition, a special sensitivity to a historical period in which ethical considerations did no longer count and the word euthanasia was used to cover up deliberate murder of helpless people [7].

It is interesting to note that in Japan, which until 1997 had no specific law on transplantation, the use of brain related criteria for the diagnosis of death was also a key issue, and hotly debated. Mainly two reasons for rejecting diagnosis of death by using brain related criteria were brought forward: the fear that interest in obtaining organs for transplantation could negatively affect the medical care of a potential donor, and that Japanese people would find it difficult to accept a definition of death that is based on diagnosing the cessation of cerebral functions [4]. The issue was hotly debated in an Ad-hoc Research Commission on Brain Death and Organ Transplantation that was established in 1990 by special legislation of the Diet (i. e. the Japanese parliament) in preparation of a transplantation law. The majority of the commission members supported the idea of integrated legislation dealing with the diagnosis of death and with transplantation. However, two members of the commission strongly opposed the acceptance of brain related criteria for the diagnosis of death by arguing that a definition of death based on diagnosing the cessation of all brain functions would not be acceptable. The final recommendation of the commission was, by Japanese standards, a very unusual document because in it the dissenting opinion was published in full, as a separate part of the final report, whereas usually such commissions publish only a unanimous or compromise opinion. Despite their objections to brain related criteria for the diagnosis of death, the minority of the Commission agreed to proceed with legislation on transplantation medicine and the removal of organs from donors who had irreversibly lost all brain functions, al-

though these humans in their opinion are still alive. The Japanese law on transplantation, based on the majority report, was proposed to the Diet already in April 1994, but it took a further three years before it was finally ratified in October, 1997.

Live donation

Although live donation of organs poses difficult moral and legal problems, these seem to have aroused less public interest than the problems surrounding death due to irreversible loss of all brain functions or the preconditions for removal of cadaver organs, and in the media there is little debate on this topic.

Until recently, live donations were restricted to kidneys because the kidney is a paired organ and one of the two kidneys – if healthy and working properly – is sufficient for leading a normal life. During the past few years, however, live donation has also become relevant with respect to the liver because it has become possible to extract a segment of the liver from a living donor and use it for transplantation to a child. This method entails greater risks for the health of the donor than the explantation of a kidney, but in some cases it seems to be the only way to save the life of a child. Since to date experience with the new method is restricted to a few hospitals only, the following considerations refer to live donation in kidney transplantation.

Since the outcome of kidney transplantations from living donors is particularly good, especially in children, the number of such transplantations is rising. But the method entails difficult ethical problems for the donor as well as for the doctor, who must perform a mutilating operation on a healthy person for the benefit of another person. Although, for the donor, the risk involved with the operative removal of one kidney is comparatively small, there is always the possibility of the remaining kidney being affected by some disease, e. g. a tumor, at a later date, so that, as a consequence of donating an organ, the donor may become dependent on dialysis or needing a transplant himself. In addition to creating a health risk for the donor, live donation is fraught with other ethical problems. Thus, the recipient may develop a feeling of guilt or excessive gratitude which may create psychological difficulties for both donor and recipient. In addition, it may not always be easy to judge between truly voluntary donation and donation under psychological pressure or with the expectation of financial or other reward. Such difficulties are least likely to occur if transplantation is between parent and child or between closely related persons. Therefore, some transplantation laws restrict live donation to adults and close relatives. But such legal differences do not sufficiently explain the great difference in the frequency with which kidney transplantation from living donors are perform-

ed in the five countries. Even if there is no legal restriction to family members, the majority of living donors are parents or close relatives. This is clearly revealed by an analysis of the Danish figures which show that in 1996 of the live donors 64 % were parents, 27 % siblings, 2 % other family members and only 7 % non-related persons [1].

With respect to the frequency of live donations there is a steep gradient between countries in the north and in the south of Europe. While in 1996 in Sweden between 35 % and 40 % of kidney transplantations were from living donors (and in Norway almost 50 %), the figure for Denmark was 25 %, for Germany 6,4 % and only 1,3 % for Spain. In Portugal, too, only very few kidney transplantations from living donors are being performed.

In contrast to the situation in Europe, transplantations from living donors predominates in Japan, and before the introduction of the new law accounted for more than 70 % of the comparatively small number of kidney transplantations performed in that country. Thus, in 1990, out of a total of 741 kidney transplantations no less than 532 were from living donors. The reasons for this high frequency of donations from living donors may partly be found in a general opposition to mutilation of a dead body and partly in the fact that most live donations take place within the tightly knit set of the family.

Allocation of organs

Allocation of the scarce organs poses the most difficult ethical problems in transplantation medicine. In all five countries, cadaveric organs that become available for transplantation are regarded as belonging to the common good and are allocated to patients on a waiting list. Since medical conditions, such as, for instance, the possible survival time of the organ, the relative importance of immunological factors or the possibility of alternative treatment, such as dialysis, differ with respect to kidney, heart, and liver, there always exist separate waiting lists for each of these organs, and the criteria for allocation from these lists are not identical. Basically, and for all organs, there are two important factors which are decisive for the chances of getting a transplant, namely the criteria for being placed on the waiting list and the criteria for selection from the waiting list.

Access to the waiting list

Contrasting with the public interest in the methods for selection from the waiting list, there is comparatively little discussion on the criteria for being placed on the waiting list. Theoretically, for those in need there is equal access to the waiting list in all five countries, and

where private medicine exists apart from a public system, there are uniform waiting lists comprising the patients from both systems. However, in actual fact, access to the waiting list largely depends on the judgement of the physician who first sees the patient, because it is he or she who will decide whether the patient is referred to a transplantation center and investigated by the specialists who then have to determine whether the patient is to be accepted for the waiting list or not. The decisions of both the physician who sees the patient first and the specialists in the transplant center are based on medical criteria but there may be considerable differences in judgement between physicians in different countries, and sometimes even between those in different centers in one country. Such differences may relate, for instance, to the question of where to set an age limit or how to value the likelihood of poor compliance. The existence and the nature of such differences in judgement indicate that even within a given country no consensus exists as to what is really covered by the term "medical criteria." In Germany, therefore, the Transplantation Law of 1997 specifically states that the transplantation centers have to decide according to guidelines issued by the German Medical Association and that the decision whether or not a patient is accepted for the waiting list has to be documented.

Selection from the waiting list

For selection from the waiting list there are some medical factors, particularly incompatibility of blood group between donor and recipient, and some other immunological constellations which make transplantation impossible. While these absolute obstacles are similarly judged in all five countries, there are other immunological constellations as well as additional factors which may be differently judged. Therefore – except for the exclusion of the above mentioned cases – considerable differences exist between the selection processes used in the five countries and even between those used by different centers in one country, for instance in Sweden. Some of these differences will be described in the following section.

Kidney

In Sweden, the guidelines for allocation are based on the principle that the scarce organs should be distributed according to need and in such a way as to secure optimal use of the limited resource. There is a central waiting list, but the patients are also on local lists of the various transplantation centers. According to the criteria of Scandiatransplant kidneys for certain medically defined cases (e.g. hyperimmunisation) are allocated from the central list. If a kidney that meets the respec-

tive criteria becomes available and is required by Scandiatransplant, the transplantation center is obliged to forward the organ. But apart from such mandatory exchange, allocation is from the local waiting lists, and the individual transplant centers are permitted to supplement the rules of Scandiatransplant. Therefore, the local rules differ somewhat between the four Swedish transplantation centers. In each of the four centers there is, for instance, a somewhat different medical appreciation of certain immunological constellations. In addition, the length of time on the waiting list is not given the same priority, and various other factors that are taken into account are not similarly weighed. With respect to age there seems to be the general rule that one tries to perform age-matched transplantations.

In Denmark, kidneys are allocated from a nationwide central- and from local waiting lists. The transplant center removing the kidneys from a donor has priority for one of the kidneys, if a patient with acceptable tissue match is on the waiting list of that center. The second kidney is allocated via the central agency to the Danish patient with the best tissue match. Any donor organ for which no suitable recipient can be found in Denmark is passed on to Scandiatransplant which in turn is linked to Eurotransplant. Since the documents describing the detailed rules are not published, it was impossible to find out which additional criteria are applied by the local transplantation centers if more than one patient with an acceptable tissue match should be found on their waiting list. The statistics reveal that during the past two decades there has been a marked increase in the number of patients between 60 and 70 years of age accepted for dialysis and for kidney transplantation [1].

In Germany, organs are allocated from a central waiting list and according to the criteria of Eurotransplant. The recipient is selected by applying a complicated algorithm taking several factors into account. One heavily weighted factor is HLA-compatibility, because this has been shown to be of particular importance for the outcome and long term success of kidney transplantation. Another factor is the frequency with which certain HLA-constellations occur [6]. Additional factors are, length of time on the waiting list, balance of national import and export of kidneys, and distance between the hospitals of donor and recipient. In 1996, 27% of the recipients were older than 54 years. For selection of children, the weighing of some of the factors differs from that used for adults.

In Spain, kidneys for hyperimmunised patients, who would reject most organs, are allocated via the central list. If the HLA-testing reveals that a kidney is suitable for such a patient, the organ has to be given to the center where that patient can be treated. Apart from such mandatory exchanges, allocation is from the local waiting lists of the transplant centers. The main criteria for selection from these lists are age, HLA-characteristics,

and body weight. With respect to the age of adult recipients, there is an upper limit of 60 and a lower limit of 20 years. If the donor is elderly, the recipient should also be elderly. If more than one potential recipient on the local waiting list fulfils the main criteria, waiting time on hemodialysis is used as an additional criterion. If, for the particular organ at hand, no suitable candidate is found on the local waiting list, the organ is passed on to another center where a suitable patient is on the list.

In Portugal, the waiting lists of the transplantation centers are coordinated by three regional Histo-Compatibility Centers (North, Central and South), and the patients are selected according to the criteria of histocompatibility. In special cases, such as extreme urgency or if the recipients are children, further clinical criteria intervene.

Résumé

In all five countries there are central mechanisms for the allocation of kidneys to hyperimmunized patients or particularly difficult and urgent cases, and in all five countries histocompatibility is a major factor for the selection of patients from the waiting list. But apart from these common features, the procedures for selection from the waiting lists differ a great deal. In all countries medical criteria are of great importance, but the various factors that enter into the decision are not identical and not always given the same weight.

Liver

Liver allocation differs from that of kidneys for the following three reasons: 1. No alternative treatment, comparable to dialysis for the treatment of kidney failure, exists for patients waiting for a liver transplant. Therefore, patients on the waiting list may die before a transplant becomes available. 2. The outcome and long-term results of liver transplantation are less dependent on good HLA-matching than kidney transplants. 3. Livers must be transplanted within few hours after beginning of cold perfusion.

In all countries one tries to allocate livers according to need and in view of the chances of success. In all five countries the selection from the waiting list is made according to medical criteria, and for the most urgent cases there are mechanisms for mandatory exchange. However, apart from mandatory exchange, the assessment of the various factors that are decisive for allocation differs between countries and even between various centers in one country. In addition, one problem has to be dealt with that does not play a role in kidney allocation: should patients suffering from a self-inflicted liver

disease (liver cirrhosis due to abuse of alcohol) be given a transplant or should other patients be preferred? And should age be a decisive factor?

In Denmark, there has been a debate on the question of whether persons with alcoholic liver cirrhosis should be allowed to have a liver transplant, and now and again this issue is raised when the discussion about health care resources and personal responsibility resurfaces in the public debate. In view of the very limited number of organs available for transplantation, a denial of liver transplants to previous alcoholics would probably have great support in the Danish public, although there seems to be no medical reason for such a policy, provided that the person in question has abstained from drinking alcohol for at least 6 months. – In the German debate on legislation, the question of whether previous life-style should be a criterion has also been discussed, and some authors have asked whether a 28-year-old patient should not be preferred to an otherwise healthy person of 60 to 65 years of age.

Heart

The situation is rather similar to that described above for liver transplantation, although a problem of self-inflicted heart disease does not exist in the same way as in the case of liver cirrhosis. However, here too, valuation of age remains an important and difficult medical problem.

The Relevance of Public Information and Debate

Providing the general public with reliable information is of great importance for transplantation medicine. Factual information through the media is as necessary as are mechanisms to provide competent answers to all questions that may arise in the public. It is assumed that the high rate of organ donation in Spain is at least partly attributable to the carefully planned transplant co-ordination system [5] and to the information policy in this country. This policy comprises regular articles and communications in the media as well as a 24-h telephone service to answer any questions that may arise about transplantation. In order to be successful, one must find the right manner in which to address the public and the individual sense of solidarity. This is particularly important when approaching the next of kin of a deceased person who is a possible organ donor. To help with this delicate task, in 1991 the "European Donor Hospital Programme" has been created by the Euro-transplant Foundation, and by 1994 this program was implemented in most European countries [8].

Although the success of modern medicine greatly appeals to the public and is often dealt with by the media,

individual persons remain sensitive to intrusions into their privacy, and most people are reluctant to become concerned with their own possible death and its aftermath. Therefore, in contrast to the positive effects of a well reasoned and careful information policy, repulsive media reports, highly emotional and controversial public debates on certain aspects of transplantation medicine, such as brain death or removal of organs, or spectacular events such as the Erlangen case in Germany, have long-lasting negative effects that lead to a reduction in the frequency of organ donation. On the other hand, once an emotional and controversial public debate like that on legislation in Germany has come to an end, an increase in the number of organ donations is noted.

Arising questions

Comparison of the regulations and procedures for the procurement and allocation of cadaveric organs has revealed considerable differences between the five European countries. Although some of these differences may be due to contingencies of historical development, the more important ones seem to result from different value assumptions. When trying to obtain a better understanding of the actual relations between value assumptions and the differences in the regulations and procedures of transplantation medicine, several questions arise which need to be answered before useful conclusions can be made. Three questions seem to be of particular interest.

What are the reasons for different family influence on decisions concerning organ removal?

Comparison of the procedures for the procurement of cadaveric organs reveals considerable differences with respect to family influence on the permission to the explantation of organs. In Sweden, for instance, the law permits organ removal unless the deceased has registered an objection or if there are close relatives who object. In Sweden as well as in Germany, the next of kin have to be asked for consent in all those cases where the deceased has not left instructions. In Denmark, the family has even greater influence and is granted the legal possibility of overriding a previous decision of the deceased and thereby preventing organ removal. The Japanese transplantation law altogether leaves it to the family to decide whether organs may be removed or not. In this context, the question arises whether these differences are only due to the fact that in some countries the family has a more domineering position than in others, or whether the special role of the family with respect to organ removal is also related to a particular

notion of the dead body of a human being, and, if so, in which way the two factors are combined. In Japan, for instance, the family traditionally has a very strong position, but in addition, mutilation of a dead body by organ removal is regarded as particularly abhorrent. And in some European countries, for instance Germany, the dead body of a human being has a very special legal status. Therefore, in order to properly understand differences of family influence in the five European countries, it will be necessary to find out more about the role of the family, the appreciation of death and the legal status of the dead body in the various countries.

How can „medical decisions“ and „medical criteria“ be defined?

Selection from a waiting list for transplantation undoubtedly entails a medical decision. But what is the definition of a “medical decision”? Is there a clear-cut definition of “medical criteria”? Of course, there are medical criteria that are based on hard scientific facts, such as blood group, immunological status, body size or weight. But are such criteria the only ones that are used in medical decisions? And if clear-cut medical criteria alone were sufficient for selecting a patient from the waiting list, why can considerable differences be found between the selection processes used in various countries, and even between the various centers in one country (Sweden)? In the German discussion [3] it has been argued, for instance, that only few of the undoubtedly medical criteria constitute absolute limits and that therefore additional criteria, which are regarded as non-medical, are used in the process of medical decision-making. One example would be compliance. From the point of view of the physician, compliance is of utmost importance for the long-term success of a transplantation, because the patient has to suppress immunological reactions by regularly attending check-ups and continuously using drugs for long periods of time, often for life. Therefore, compliance is of great medical importance, and this may lead to preferring patients with a prognosis of reasonably good compliance. But is prognosis of good or poor compliance always possible? And is it a medical criterion in the strict sense of the word? Is it not, in addition to the inborn character of the patient, also dependent on factors such as family situation, social integration and the intensity of help that can be provided by others?

Similar questions can be raised with respect to lifestyle. Differences exist, for instance, with respect to the treatment of liver cirrhosis due to abuse of alcohol. While in some centers such patients are considered for liver transplantation, they are excluded in others, even if treatment for withdrawal has been successful, at least temporarily. Transplantation may be the only help for

such a patient, but survival time may be short if he or she relapses into earlier habits. Therefore it can be argued that the liver could be put to better use if given to a patient with a healthier life-style. But is this an exclusively medical argument? – And what about age? Are there reasons why, under comparable conditions, a young patient of 28 years should be preferred to an otherwise healthy patient of 60 or 65 years of age?

Such considerations indicate that the definition of “medical criteria” is not as unequivocal as one would wish it to be. What is a medical criterion for the physician may be judged, by a sociologist, as a value-biased-loaded and not truly medical criterion. Thus, the comparative study on transplantation indicates that the understanding of what the true characteristics of a medical decision are, are by no means unanimous, and may differ between the cultural traditions of the five countries taking part in this study. Therefore, the various notions of “medical decisions” and “medical criteria” need to be studied in a more systematic and detailed way. A separate study on these questions is being carried out within the EU-project by G. Hermerén.

What is the relevance of „closeness and distance“ for medical decisions?

In a normal doctor-patient-relationship, the doctor is concerned with the patient as a unique individual that must be treated in the best possible way and according to his or her specific personal needs. Thus, when a transplantation becomes necessary, the doctor can take all the necessary steps to have the patient considered for inclusion in the waiting list. But once the patient is on that list, the classical doctor-patient-relationship no longer applies, because selection from the waiting list requires that several patients be considered and weighed up against each other. If an organ becomes available for transplantation and is found to be suitable for more than one patient, a decision has to be made who will be given that organ, and not every patient can be helped in the best possible way. In some European countries, decisions concerning selection from the waiting list for organ transplantation are made far away from the patient by applying a complicated algorithm that takes a number of measurable factors into account. But in other

countries, only few decisions are made in this centralized and impersonal way. Instead, the decisions are made closer to the patient by selection from a local list. Both methods can be defended with good arguments: in the case of the centralized decision, a maximum of impartiality is achieved, in the case of a decentralized decision, closeness to the patients enables the physician to consider additional factors which may be of relevance but cannot be taken into account by the algorithm used for central decision making. Therefore, it is not easy to decide whether centralized or decentralized decision making should be preferred for selection from the waiting list.

In this context, the general question arises of how the outcome of decisions in the health care system is affected by the closeness or distance of decision making. Since little is known about this problem, the influence of closeness or distance on medical decision making requires special investigation. A separate study on these questions is being carried out within the EU-project by B. Forsman.

Conclusion

Comparison of transplantation medicine in five European countries reveals important differences such as, for instance, the influence of the family on organ donation, or the frequency of kidney transplantations from living donors. So far, these differences are not well understood. They are at least partly related to different cultural traditions and value assumptions which pose several questions that require further investigation. The findings so far obtained, strongly indicate that, as long as these questions have not been systematically and thoroughly analyzed, it would be premature to issue common guide lines for Europe that would affect value assumptions, because transplantation medicine is an emotionally highly sensitive subject everywhere, and disturbance of the public would do more harm than good.

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