

Increasing the number
of organ donations:
A pressing issue for
transplant medicine
in Germany

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A BACKGROUND AND SUBJECT

For some two decades, organ transplants have been standard practice for the treatment of a number of serious disorders involving organ failure. Since then, many patients have owed either their lives or a decisive improvement in their quality of life to transplant medicine. However, year after year patients die because an organ is not available promptly, even though a transplant would probably have saved them. While the shortage of organs is a chronic problem for transplant medicine in all countries, it is particularly severe in Germany. Comparative statistics show that the number of organ donations per head of population in Germany is smaller than in other countries. When the Transplantation Law (TPG) came into force in 1997, it was hoped that organ donation would increase, but this has not happened. There are indications that this state of affairs is due not only to deficiencies in the organization of the health system, but also to the relevant legislation, which provides that organ donation after death is conditional on an explicit declaration of consent by the donor or his¹ relatives.

The ethical and legal issues raised by living organ donation are not discussed in this Opinion, because a greater potential for ethically acceptable mitigation of the organ shortage is felt to lie in organizational improvements and in the expansion of post-mortem organ donation.² The central question in relation to post-mortem organ donation is whether it is ethically and constitutionally acceptable, in order to relieve the shortage of organs, to amend the current statutory provisions concerning the need for explicitly declared consent on the part of donors or their relatives. The present debate involves various proposals,

¹ For simplicity, the masculine form is used in this Opinion for both sexes.

² Whereas only a few organs or parts of organs (kidneys or segments of the liver, lungs and pancreas) can potentially be taken from living donors, in principle all transplantable organs can be harvested from a deceased individual. Again, living organ donation, which always involves a certain health risk to the donor, raises particular ethical problems.

all of which seek to strike a balance between the potential donor's right of self-determination, the desire to save lives and to reduce suffering in others, and established principles of the health system such as equal access to health-care benefits. The National Ethics Council ultimately proposes a two-tier model combining elements of a system of declared consent (opt-in system) with aspects of an opt-out (presumed-consent) system. This would require the State to ensure that its citizens:

1. are systematically called upon to make a personal declaration as to whether they agree to organ donation; and
2. are made aware that in the absence of a declaration organ removal is legal unless the relatives object.

B THE SITUATION OF TRANSPLANT MEDICINE IN GERMANY

The first organ transplants were carried out in the 1950s. They were experimental treatments which, owing to immunological tissue incompatibility, could succeed only if the transplant donor and recipient were genetically identical – that is, if they were monozygotic (identical) twins. During the course of the 1960s, control of immune defence became increasingly feasible, so that rejection reactions could be prevented. As a result, transplants between genetically different individuals also became possible. However, to this day recipients of a donor organ remain dependent for the rest of their lives on immunosuppressive drugs, which may not only have harmful side-effects but also increase the likelihood of secondary disorders. Even so, after considering the advantages and disadvantages, the vast majority of patients opt for a transplant.

Transplant medicine grew out of its experimental phase some two decades ago and is now professionally established as a standard medical procedure throughout the world. In Germany, a total of some 79 000 organs have been transplanted since 1963. Organ transplants are now regarded by the vast majority of the population as an accepted and expected normal medical treatment. Surveys³ show that more than three quarters of respondents have a positive view of organ donation (organ transplantation).

The legal foundation of organ transplantation in Germany is the Transplantation Law (TPG) of 5 November 1997. This provides that organs can be retrieved only after the donor's death has been established "by rules that reflect the latest state of knowledge in medical science". The task of drawing up these rules is assigned to the German Medical Association (Bundesärztekammer). The Transplantation Law further provides that organ retrieval is impermissible in the absence of a prior

³ That is, surveys in Germany. For more detailed information, see footnote 25.

finding of whole-brain death – that is, final and irreversible failure of all functions of the cerebrum, cerebellum and brainstem (the brain death criterion). The TPG thus confines itself to specifying brain death as the precondition for organ removal, and refrains from a more detailed definition of its own of the point in time at which a person must be deemed to be dead. However, in the German Medical Association's guidelines on the subject, whole-brain death is equated with death in the scientific and medical sense.⁴ To be sure, the brain death criterion has again and again been the subject of debate concerning the correct understanding of the death of a human being and the appropriate anthropological significance of the brain as the organ that integrates the individual organ functions into the overall activity of the organism. At present, however, a wide measure of agreement exists in society on the legitimacy of this criterion of death. Brain death is then held to indicate that a person is dead not because the functions of consciousness can be localized in the brain, but because brain functioning is an indispensable prerequisite for the maintenance of mind-body unity.

The Transplantation Law established a legal foundation for organ donation and transplantation in Germany. However, despite the hopes placed in the Law, it did not result in an adequate supply of donor organs. In 2006, 1259 dead subjects were available for post-mortem organ donation (3.9% more than in 2005);⁵ a total of 3925 organs were retrieved from them (3777 in 2005).⁶ However, the number of organs implanted in 2006 (4032) exceeded the supply accruing in Germany itself;⁷ the balance was made up by organs from other countries provided through the Eurotransplant Foundation.⁸ There is, then, a severe shortage of donor organs in Germany. As a result, every year some

4 Wissenschaftlicher Beirat der Bundesärztekammer 1998: A 1861.

5 Deutsche Stiftung Organtransplantation 2007.

6 Ibid.

7 Ibid.

8 In addition to Germany, the members of Eurotransplant are Belgium, the Netherlands, Austria and Slovenia.

1000 persons on the waiting list for a transplant die because a suitable donor organ cannot be made available to them in time.⁹ The shortage concerns all the organs specified in the Transplantation Law as subject to compulsory allocation, although to different extents; these organs are the kidney, liver, heart, lung, pancreas and intestine, for all of which the number of patients newly registered for a transplant in 2005 significantly exceeded the number of transplants actually carried out.¹⁰ As to the medical prerequisites and the likely success of a transplant, however, the situation differs from organ to organ.

Like dialysis, kidney transplantation is now accepted as a standard procedure in renal replacement therapy (RRT); both can enable patients to survive for years or even decades. A kidney transplant is indicated for advanced chronic kidney failure. The underlying conditions for which transplants are carried out in adults are type 2 diabetes (maturity-onset diabetes; about one third of all transplant cases), hypertension (with nephrosclerosis; approximately a quarter of all cases) and chronic nephritis (about a quarter of all cases). Except in children, congenital malformations and "systemic disorders" constitute the underlying condition in only a small number of cases. The medical success of a kidney transplant depends not only on the degree of donor-recipient tissue compatibility but also on the kind of organ donation: living donation is found in this case to be superior to post-mortem donation, and accounted for just under 20% of kidney transplants in 2005.¹¹ Another relevant factor is the frequency of prior transplants: first transplants give better results than second transplants, and so on.

The quality of life of many patients who have a kidney transplant is appreciably enhanced, even when compared with the common alternative of years of dialysis, with the associated restrictions. Recipients of a donor kidney are often able to enjoy a

9 As at 31 December 2005, about 11 500 persons were on the waiting list for an organ transplant in Germany (Eurotransplant International Foundation 2006).

10 Deutsche Stiftung Organtransplantation 2006: passim.

11 Ibid.: 28.

quality of life that is not inferior to that of the population at large.¹² In the majority of instances, kidney transplants not only have demonstrably favourable effects on patients' bodily sensations and physical performance, but also enable them to participate more actively in social life, thus resulting in an overall increase in psychological well-being.¹³ Furthermore, kidney transplants present an advantage in terms of survival compared with many years of dialysis: kidney transplant patients live longer than those on dialysis. The economics, too, favour kidney transplantation: long-term dialysis treatment is appreciably more expensive than a transplant, even when the necessary follow-up treatment is taken into account. Many organ recipients are able to resume their former occupations.

Like all transplants, however, kidney transplants are not devoid of sometimes significant risks to patients. Chief among these is loss of the transplanted organ. The failure of a transplant may be due to a chronic rejection reaction, to harmful side-effects of the immunosuppressive drugs (nephrotoxicity), or to a recurrence of the underlying condition that necessitated replacement therapy. The five-year transplant function rate in 2005 for organs of cadaveric origin was 71%, compared with 84% in the case of living donation.¹⁴

The difference between the number of kidneys required and that available for transplantation is substantial. In 2005, 2712 kidney transplants were carried out, while 2730 new patients came on to the waiting list. The total number of patients waiting for a new kidney was 8853.¹⁵ In other words, as in previous years, more than three times as many people were waiting for a new kidney as the number of organs available for allocation per year. This situation is unlikely to have changed significantly since then. Liver transplant patients, too, are found to experience a significant post-operative improvement in quality of life, in terms both

of objectively measurable physical function and of subjective appreciation of social activities, physical health,¹⁶ sexuality, conduct of normal daily activity and psychological health. The principal indications for a liver transplant are advanced hepatic cirrhosis, acute liver failure, liver tumours and metabolic disorders. In the case of acute liver failure in particular, urgent action is essential, since alternative therapies such as the "artificial liver" are still at the experimental stage. The factors that determine the success of a transplant are the underlying disorder and the patient's pre-operative clinical condition: one-year survival ranges between 90% where the initial situation is relatively stable and 70–80% in the case of an emergency transplant. With liver transplants, chronic rejection leading to loss of the transplanted organ is relatively uncommon.

The number of liver transplants carried out in Germany in 2005 was 976.¹⁷ Living donation is possible in the case of the liver too, as only segments are transplanted. The proportion of living donations accounted for by segments in 2005 was 8%. The five-year transplant function rate for organs from post-mortem donation in Germany in 2005 was 60%, while the three-year transplant function rate for living donations was 66%.

Heart transplants, which are by their nature possible only by way of post-mortem donation, are mainly indicated for the various forms of advanced cardiac insufficiency. As an alternative to a heart transplant, mechanical techniques capable of taking charge of all cardiac functions over a period of several months can be used for short- to medium-term cardiac function support. Overall, heart transplant patients too are found to enjoy significant improvements in quality of life. Some have even recorded astonishing feats of physical prowess, such as climbing Kilimanjaro or the Matterhorn. Yet, notwithstanding a favourable assessment of health and physical performance, especially when compared with the suffering experienced before

¹² Robert-Koch-Institut/Statistisches Bundesamt 2003: 28.

¹³ Schulz et al. 2002: 791.

¹⁴ Deutsche Stiftung Organtransplantation 2006: 28.

¹⁵ Ibid.: 26.

¹⁶ Breyer et al. 2006: 18 ff.

¹⁷ Deutsche Stiftung Organtransplantation 2006: 35.

surgery, the everyday lives of transplant patients, in tasks such as shopping, climbing stairs or housework, are often subject to appreciable restriction.¹⁸ Since the heart has not only physiological but also symbolic significance, a heart transplant also calls for particular post-operative psychological adaptation.

In 2005, 396 heart transplants – including 15 combined heart-lung transplants – were carried out in Germany, while the number of new patients coming on to the waiting lists was about twice this figure. The number of heart transplants is found to be in long-term decline.¹⁹ This trend is attributable partly to the shortage of hearts available from deceased subjects, but also to a change in the medical indications for a transplant, due to improved drug treatments for heart disorders and the routine application of cardiac support systems. In the initial period after a heart transplant, the survival rate is substantially determined by rejection reactions and infections, whereas in the longer term the principal factors are the side-effects of immunosuppression and the danger of coronary heart disease. The five-year function rate after a heart transplant is about 69%.²⁰

A lung transplant is indicated for a number of advanced disorders of the lung structure or pulmonary vessels that lead to untreatable terminal pulmonary failure. Depending on the condition, either one or both pulmonary lobes may be transplanted; in some cases, a combined heart-lung transplant is necessary. Except in the case of donations for children, in which individual lung segments obtained from a living donor can be transplanted, lungs, or parts of lungs, are donated only after death. In 2005, 262 lung transplants were carried out in Germany, while just under 400 new patients were registered on the waiting list. The trend here is increasing, so that a significant difference persists between the number of patients registered and the number of transplants that can be conducted.²¹

¹⁸ Schulz et al. 2002: 785 ff.

¹⁹ Deutsche Stiftung Organtransplantation 2006: 32.

²⁰ *Ibid.*: 34.

²¹ *Ibid.*: 39.

The risk of post-operative infection is high, as the lung, with its large surface area, is exposed to the environment and the natural cough reflex has been lost owing to the lack of nerve connections to the transplanted organ. The choice of suitable organs is therefore a crucial factor in the success of a transplant. The five-year function rate of transplants in 2005 was 54%.

Patients awaiting a lung transplant always have a long and painful medical history with greatly reduced tolerance of exertion. Following a lung transplant, patients' health-related quality of life is in general significantly improved. This is true at least of patients who do not suffer from bronchiolitis obliterans – that is, fibrous scarring of the donor organ. This chronic condition, which appreciably impairs health-related quality of life, affects nearly half of all long-term survivors after a lung transplant. Another finding is that, notwithstanding a significant improvement in post-operative quality of life, lung transplant patients remain subject to limitations in terms of self-esteem, psychological well-being, emotional role function and body image.²²

Although a pancreas transplant for replacement of the hormone-producing function of the organ is indicated at an early stage of an insufficiency, owing to the shortage of donor organs and the side-effects of immunosuppression this procedure is conducted at present only in the event of additional organ complications such as disturbances of kidney or nerve function or disorders of vision in the advanced stages of the condition, or where problems arise with insulin therapy, and even then as a rule in combination with a kidney transplant. Pancreas transplants normally use organs from deceased donors, although a small number of partial transplants from living donations have already been carried out.

In view of the high technical risk involved in a pancreas transplant owing to the production of large quantities of aggressive digestive secretions, attempts have recently been made to transplant only the insulin-producing islet cells, although so far

²² Schulz et al. 2002: 787 ff.

with only limited success.²³ The overall risk of the various complications of diabetes directly attributable to the operation is significantly higher than with transplants of other organs: the five-year function rate of pancreas transplants is 66%. In 2005, 165 pancreas and combined pancreas and kidney transplants were carried out in Germany. In spite of the risks mentioned, patients rate the operation as favourable to their social interaction and vitality.

Transplants of the small intestine are rare, only two such operations having been carried out in Germany in 2005. These constitute an experimental form of transplantation that cannot be compared with ordinary therapeutic transplants. Small intestine transplants are indicated principally for certain forms of short bowel syndrome following operations for inflammatory disorders of the intestine, as well as in the case of complete venous thromboses of the vessels of the small intestine.²⁴ As with lung transplants, there is once again a high risk of infection owing to the large surface area of the small intestine, while the transplanted organ is also susceptible to rejection.

²³ Breyer et al. 2006: 22.

²⁴ Deutsche Stiftung Organtransplantation 2006: 41.

C REASONS FOR THE SHORTAGE OF ORGANS

1. Initial situation: non-utilization of the full potential for donation

In societies with comparable living conditions, the percentage of deceased persons satisfying the criteria applied by transplant medicine for post-mortem organ donation may be assumed to be subject to no more than negligible fluctuation. For this reason, the fact that organs are harvested from fewer deceased subjects in Germany (per million population) than in neighbouring European countries shows that the potential donor pool in this country is not fully utilized. In theory, one explanation might be that organ retrieval that is medically possible and indicated cannot be carried out in Germany because people are unwilling to donate. However, the available figures do not bear out this explanation. It is true that some members of the public do indeed have reservations about organ donation. Some people are concerned that their bodies should be buried in unutilized form, while others do not want their relatives to be burdened with the procedures of organ retrieval in the phase of parting and mourning. Nor is the brain death criterion universally accepted, and it is sometimes suspected that in some cases not everything medically possible is done for patients who are potential organ donors. These reservations must be taken seriously and respected, and they cannot be completely disposed of even by information campaigns or by increasing the transparency of transplant medicine. However, such considerations induce only some 20% of the population to declare themselves unwilling to be organ donors. On the other hand, more than 80% of the population of Germany are in favour of organ donation in general, while two thirds declare themselves willing in principle to donate organs themselves; about 10% are undecided in both cases.²⁵

²⁵ In a Forsa survey in 2003, 85% of respondents stated that their attitude to organ donation as such was "positive rather than negative", while 7% were

Admittedly, declared willingness to donate as revealed by the surveys is at first sight only slightly above the actual consent rate observed for organ donation: in 2005, organs were retrieved from 61% of the potential donors notified by hospitals.²⁶

However, this figure is misleading. It is high because potential donors deemed unwilling to donate on the basis of interviews with the donors themselves or their relatives or of other indications are usually not reported in the first place. On the basis of the total number of potential donors (including those not reported), the actual number of organ donations amounts to less than 61% of all possible donations. This suggests that the declared willingness to donate (68%) is indeed not fully utilized.

There are other reasons too for assuming that the public's willingness to donate is not fully utilized by current practice. After all, personal willingness to donate is not a fixed magnitude. According to a Forsa survey carried out in 1999, the relevant figure for respondents who declared themselves to have thoroughly considered the issue of organ donation was 78%, whereas this proportion fell to 44% for those who had not concerned themselves with the subject at all.²⁷ It is quite likely that, given appropriate conditions (in particular, more extensive public information), many of the don't knows and negative respondents in surveys could be won over for organ donation.

For this reason, public attitudes to transplant medicine and organ donation are not the principal reason why the number of post-mortem organ donations is smaller in Germany than in

"negative rather than positive" and 8% were "neutral". The proportion who were in principle willing for organs to be taken from their own bodies after death was 68%; 21% declared themselves unwilling, while 11% were undecided (Breyer et al. 2006: 143 and 151, with additional references and discussions of survey results).

²⁶ Just under 6% of cases were based on the existence of an organ donor card; in about 90% of cases, the basis was the deceased's wish as orally expressed or as presumed by the relatives; while in some 4% of cases, the relatives opted of their own accord for organ donation, in the absence of either a written or an oral declaration of the deceased's wishes, as well as of any indication of his presumed wishes (Deutsche Stiftung Organtransplantation 2006: 10).

²⁷ This was true of 32% of respondents. The refusal rate was 14%, with 8% don't knows (Gold et al. 2001: 21, cited in Breyer et al. 2006: 152).

neighbouring European countries. There are two main potential reasons for the organ shortage in this country: first, the health system is affected by organizational deficiencies and administrative shortcomings which lead to problems in the identification and reporting of potential donors in hospitals; and, second, the legal provisions prevailing in Germany limit the number of potential organ donors in Germany to a greater extent than in other countries, in so far as organ retrieval is permitted only on the basis of an explicit declaration of consent by the donor or his relatives.

2. Organizational reasons for the shortage of organs

Bottlenecks in the organization of the transplant process arise mainly in the identification and reporting of potential donors at hospitals. Although reporting is compulsory under the Transplantation Law, in 2005 only 45% of hospitals with intensive care units participated in the process of organ donation – that is to say, at least contacted the relevant coordination centre.²⁸ This unsatisfactory state of affairs is due both to the absence of incentives for hospitals to involve themselves in organ donation and to the lack of sanctions for not doing so.

Perhaps the main disincentive is the current fixed-rate system of refinancing. The new system of compensation for donating hospitals, dating from 2004, provides for a staged refinancing model with payments depending on the progress of the retrieval process. However, the amounts laid down do not always cover the actual costs incurred. If the expensive process of brain death diagnosis does not lead to a finding of brain death, so that organs cannot be harvested, no further "transplant-induced" refinancing is forthcoming. Furthermore, the fixed rates do not cover the additional measures often desired by transplant centres

²⁸ Deutsche Stiftung Organtransplantation 2006: 8.

for assessment of the quality of organs and improvement of their transportability. To avoid the associated financial risks, hospitals may feel that they have no alternative to refraining from the reporting of potential donors.

Given this financial situation, organ retrieval is a problem for small and medium-sized hospitals in particular. Because organ removal often has to be carried out at night and is virtually impossible to allow for in duty rosters, substantial organizational rescheduling of shifts is inevitable. Since medical staff given time off in lieu are unavailable on the following day, planned operations have to be postponed. This not only results in direct financial loss on the one hand and uncertainty and dissatisfaction in other patients on the other, but may also indirectly tarnish the hospital's reputation.

Besides the financial and organizational aspects, another significant determinant of a hospital's participation in organ donation is the motivation of the doctors and nurses in the intensive care unit. The primary task of the medical staff of an intensive care unit, which also determines their understanding of their professional role, is the relief of suffering and the saving of lives. Since neither is any longer possible in the case of a potential organ donor, donor identification and preparation for possible organ retrieval are more likely to receive lower priority than the treatment of patients with good prospects of recovery. In a situation in which patients with prospects of a successful treatment outcome are competing with potential donors for the scarce resource of the attention of nursing staff, structural considerations mean that the latter will come second. This will have significant effects at the time when concrete measures to prepare for organ removal would need to be taken, if not before. Again, the "ordinary" patients on their own wards, with their illnesses and hopes for recovery, are constantly and concretely before the eyes of the doctors and nurses. Patients on the waiting list who might profit from a transplant at the end of a complex process, on the other hand, are from this point of view an abstract magnitude whose suffering is remote and

whose recovery is linked only indirectly to the work of the hospital where organs are removed.

Another difficulty of organ donation for clinical staff is presented by interviews with the relatives of potential donors. The Transplantation Law requires such an interview to be conducted in the absence of a written declaration of consent to organ removal by the potential donor. However, even where a written declaration of consent does exist, the relatives are consulted. Such meetings always take place in an emotionally difficult situation. After the doctors have had to admit defeat in the struggle for the patient's life and informed the relatives of the patient's death, on account of the intense pressure of time for organ retrieval there remains only a brief interval for them to confront the relatives with the request for consent to this measure. This calls for a high capacity for empathy, consistent with the relatives' sense of bereavement. Furthermore, contradictory requirements apply to the course and result of the interview: on the one hand, ethical considerations dictate that it must be conducted neutrally as to its result, without forcing the relatives in a particular direction, while, on the other hand, those involved in the transplantation process expect as high as possible a consent rate from the relatives.

Various approaches, comprising a mixture of positive incentives and negative sanctions, have been proposed to improve this unsatisfactory situation. The main positive incentive that suggests itself is a financial provision that would guarantee that all the costs incurred by an organ-retrieving hospital would be covered. These should include all the separate, individual actions involved, while, in addition, if the preparatory measures for removal have to be broken off at any time, this must not result in failure to meet all of the expenditure arising.

Another perfectly feasible idea would be to offer hospitals incentives for the reporting of potential organ donors. However, such incentives must on no account be detrimental to the life-sustaining care of the patients concerned. Nor should additional sanctions for hospitals unwilling to cooperate be ruled out in advance.

A further important step would be the appointment of transplant coordinators in the relevant hospitals, as is already the practice in some Federal Länder. Such an approach is based on the consideration that the personal dedication of individuals and the establishment of links, in terms of personnel and on a regional basis, between the relevant actors (hospitals, the coordination centre and transplant centres) are crucial to successful organ donation. Furthermore, a coordinator specifically appointed to deal with matters of transplant medicine, whose voice would be vital both in fundamental decision-making in the clinic and in bedside decisions, could make for the integration of, and the striking of an appropriate balance between, the ethical, psychological, legal and organizational aspects of the transplant process.

3. The effects of the current opt-in system in Germany

Under the wide opt-in system provided for in the Transplantation Law, the permissibility of a possible organ removal is determined primarily by a declaration by the potential donor made while he is still alive and documented in writing, preferably in an organ donor card – that is, his consent or refusal. If written documentation of this kind is not available – because it does not exist or cannot be found – it is the responsibility of the next of kin to indicate whether the deceased has expressed a view orally on the question of organ removal; consent, or, where applicable, objection, to organ donation is not recorded in a central register. If the deceased has not made a declaration during his lifetime, the decision is made on the basis of his presumed wishes. For this purpose, the relatives must consider everything that might provide an indication of these wishes. It is only at a third stage that the relatives can make a decision, at their discretion, on the basis of their right to determine the treatment of the deceased's body.

The emphasis in this system is on the right of self-determination; its provisions ensure that any reason a person might have for objecting to post-mortem organ donation for his own person is immediately taken into account. At the same time, however, organ removal is then not necessarily permissible simply by virtue of a willingness to donate: anyone who actually wishes to donate his organs or at least has no objection to their being removed after his death, but fails to make an explicit declaration to that effect, will become an organ donor only if his relatives agree to the donation. A high proportion of passive willingness to donate may nevertheless be expected. Only about a fifth of those who say they are prepared to donate have documented their willingness in an organ donor card. This discrepancy cannot be explained by claiming that surveys do not record actual willingness to donate because respondents only give answers that they regard as socially acceptable. It in fact reflects a variety of reasons for not doing something although one has no fundamental objection to it – for instance, one cannot be bothered to deal with the formalities involved in obtaining an organ donor card; or one postpones, forgets or represses the decision because one does not like to think about one's own death and would rather not make any concrete advance arrangements in connection with it. The practical consequence is always non-satisfaction of the requirement that an organ donation that is in fact desired, or to which there is at least no objection, shall become legally permissible on the basis of a declaration by the deceased himself.

The involvement of the relatives under the wide opt-in system cannot fully offset the consequences of the passivity of potential organ donors. In the absence of a donor card or other form of declaration, some relatives are more likely to assume that the deceased did not wish organs to be removed from his body. If they therefore do not declare their consent explicitly, organ removal is impermissible even if the deceased has failed to make a declaration for other reasons. In addition, the relatives may feel that additional strain is being imposed on them if they are called upon to determine the presumed wishes of the deceased regarding

organ donation or to make a decision themselves. In cases of doubt, they will follow the logic laid down by the Transplantation Law with its opt-in provisions, and refuse to allow organs to be removed in the absence of consent by the donor.

Organizational improvements will most likely be unable fully to eliminate the adverse effects of the opt-in system on organ availability; on the other hand, a change in the legal rules governing permissibility will also not by itself suffice to overcome the shortage of organs. It therefore seems inappropriate, in considering possible ways of reducing the shortage of organs, to play off the possible organizational improvements against a possible change in the provisions governing the permissibility of organ donation. Some indication of the influence of legal permissibility provisions is afforded by the fact that, in countries where post-mortem organ removal is automatically permissible if the deceased or his relatives have not objected (the opt-out system), the average number of organ donations is higher than in countries such as Germany where the opt-in system is applied. In Belgium and Austria, for example, the number of post-mortem organ donations per million population is well above 20 – in Spain it is in fact over 30 – whereas the donation rate in Germany is stagnant at about 15. Nor can this result be dismissed by pointing to the high level of regional variation in Germany – for instance, even under the opt-in system, significantly higher donation rates have been recorded in some Federal Länder, such as Mecklenburg-West Pomerania, which has often achieved figures of the same order as those recorded in Spain.²⁹ Regional variations are also observed in the countries with an opt-out system, but the overall average around which the figures vary is higher than in Germany. In view of this situation, a review of the legislation applicable in Germany appears to be indicated. In the following sections, some alternative possibilities are subjected to ethical evaluation and considered in terms of their legal permissibility.

²⁹ Deutsche Stiftung Organtransplantation 2006: 18.

D THE RANGE OF ALTERNATIVES TO THE PRESENT OPT-IN SYSTEM

There are a number of possible ways of redefining the permissible pool of potential organ donors in order to increase the supply of available organs. These alternatives diverge to different extents from the current opt-in system, which gives priority to the donor's right of self-determination.

The greatest degree of clarity as to a potential donor's wishes would be obtained if all members of the public were required to declare whether they consent or object to organ donation after their death (compulsory declaration, or mandated choice). Apart from the decision for or against organ donation, provision could also be made, in a less rigorous declaration-based system, for the possibility of not expressing a view. In this case, however, legal provisions would be necessary to decide whether or not organ removal is permissible where no view has been expressed.

Under the opt-out (presumed-consent) system, anyone who has not specifically objected could be considered for organ donation after death. Unlike the opt-in system, this solution would place the onus of making a declaration on those who do not wish to be organ donors. A narrow form of the opt-out system would involve making organ donation dependent solely on refusal by the deceased; in a wide opt-out system, on the other hand, the relatives would also have the right to object to organ removal.³⁰ A third group of solutions, whose various forms are described, for instance, as the "club solution", the "solidarity model" or the "reciprocity model", are based on the consideration that it is unfair for a person to refuse to be an organ donor himself but nevertheless to rely on the willingness of others to donate should he himself be in need. To combat this kind of "free-rider mentality",

³⁰ The narrow opt-out system is applied in countries such as Italy, Luxembourg, Portugal, Slovenia, the Czech Republic and Hungary, while the wide opt-out system operates in, for instance, Belgium, Finland, Norway and some Swiss cantons. However, in some countries where the law provides for a narrow opt-out system, a wide opt-out system is actually practised – e.g. in Austria and Spain (see below).

the advocates of such solutions suggest that those who do not agree to organ donation under a opt-in system or who refuse to donate under an opt-out system should be prohibited by law from receiving an organ themselves should the need arise, or at least be relegated to a position further down the waiting list. At any rate, those who declare themselves willing to be organ donors should be assigned priority in the waiting list. Preference could also be given to potential donors by granting all organ donors the right to restrict the group of potential recipients of their organs in such a way that potential donors receive priority in organ allocation if they themselves should need a transplant. All these proposals ultimately preserve the right of self-determination of potential donors – but then certain decisions can be made only subject to the acceptance of disbenefits to the person making them.

Another proposal with the character of an “incentive” for organ donation is that potential donors should be offered financial advantages, or even payment. A solution of this kind need not degenerate into a free market for organs on which the rich enjoy preference and the poor are impelled to sell off their health. One suggestion is the payment of amounts fixed by the health insurance funds for the relevant organs, or the meeting of funeral expenses in the case of post-mortem organ donation.

The most radical alternative would certainly be to require the entire population to donate organs after death whether or not they consent. This solution is often described as an “emergency system”. The term “social obligation system” would be more precise, as the underlying notion is that post-mortem organ donation is a duty to the community and that it is therefore justifiable for the community to have the bodies of the dead at its disposal for organ donation for the benefit of patients in need. In this system, neither advance self-determination by the deceased nor the needs and wishes of his relatives are taken into account.

All the alternatives to the opt-in system mentioned above are no doubt in principle capable of mitigating the shortage of organs. In the social obligation system, this already follows from

the fact that anyone suitable from the technical medical point of view to act as an organ donor may then be legally called upon to donate. A solution that requires every member of the public to make a declaration has to date not been introduced in any country. For this reason, no empirical data are available as to the possible effects on the number of organ donations achieved. Since surveys show a high degree of willingness to donate among the public, it is surely legitimate to expect that a high proportion would explicitly declare their personal consent. However, another possibility is that the demand to make an explicit declaration might have negative repercussions on willingness to donate, because people who are basically prepared to donate organs might assume a defensive attitude if they were put under pressure to commit themselves. A defensive response of this kind would be avoided if those concerned were formally invited to make a declaration, but were free not to do so without incurring sanctions. Another argument in favour of a simple invitation is that a formal legal obligation would involve a substantial degree of administrative complexity, especially in regard to possible sanctions, but also with respect to the recording of changes in people’s wishes.

The opt-out system yields higher donation rates because the number of persons who explicitly object to organ removal after death is in fact very small. This is borne out by the experience of other countries. There are a number of possible reasons for failing to register an objection:

1. It is a matter of everyday experience that people are less likely to perform a specific act – registering an explicit objection – than to do nothing.
2. A system formulated as the “norm” is likely to be accepted as correct.
3. The decision may be deferred, or people may be reluctant to take the trouble to document it.
4. People may not be sufficiently aware that they can register an objection.

In the case of the opt-out system, a larger number of organ donations than with the wide opt-in system is still obtained if the relatives are involved in the decision on donation. This is borne out by the experience of Spain and Austria. Although the letter of the law provides for a narrow opt-out system, what is actually practised is a wide one. In Austria, the relatives are only asked whether the deceased has made an objection recognized under the relevant law; however, the intended organ removal is not carried out if the relatives categorically object. In Spain, every effort is manifestly made actually to obtain the relatives' explicit consent.³¹ One reason why a larger number of organ donations is achieved even under the extended opt-out system is no doubt that the relatives are not required to take any specific action as a condition for the permissibility of organ removal. In a situation that is in any case extremely traumatic for them, they are in effect able simply to let matters take their course with regard to the removal of organs. They can take the fact that the deceased has not registered an objection to signify that he would have nothing against organ donation, and they may for this reason feel it appropriate not to object (or, as the case may be, to consent) themselves.

Reciprocity solutions can be combined with all the models so far considered. Unlike the compulsory declaration system, they are not based on a compulsion to commit oneself one way or another, but on the motivation of expected self-interest. However, they break with a long-established tradition in Germany and other countries – namely, with the principle of equal access to health-care resources irrespective of an individual's prior actions. In addition, they make organ allocation even more complicated than it already is. Lastly, the problem of fairness resulting from

³¹ Surveys indicate that about one in every two Spanish citizens would regard it as an abuse of power if the organs of deceased persons were actually retrieved as permitted by law without involving the relatives. The information on Spain was provided by Beatriz Domínguez-Gil, Organización Nacional de Trasplantes, Madrid, and on Austria from Theresia Unger, Österreichisches Bundesinstitut für Gesundheitswesen.

a revocation at short notice (which cannot be prohibited for constitutional reasons) is virtually insoluble: for instance, a person who was willing to donate for most of his life but then takes advantage of the possibility of revocation shortly before his death would have had the option, during his lifetime, of receiving preference in the allocation of an organ had he needed one; yet his present refusal means that he ceases to be a potential organ donor. In view of all these ethical problems, the reciprocity model will not be considered further in this Opinion.

The same applies to a solution that seeks to obtain consent for organ removal through financial incentives. This approach is opposed by widely shared reservations about the commercialization of the human body. Furthermore, the intrusion of commercial considerations might conceivably weaken the altruistic motivation to donate organs and thereby, at least in the short term, reduce rather than increase the availability of organs.

The compulsory solidarity solution (emergency system) should not be considered as a means of increasing the supply of organs. Given that a human corpse is not an object like any other, but the mortal remains of a person, the imposition of such a duty of solidarity would constitute a profound encroachment on the right of self-determination of those concerned and possibly also on their freedom of faith or *Weltanschauung*. An encroachment of this kind is questionable if only because there are less drastic approaches to relieving the current shortage of organs. The combination of a declaration-based system – that is, an invitation to declare oneself for or against organ donation – with an opt-out system is one such approach. For this reason, the National Ethics Council will consider only this possibility in the remaining sections of this Opinion. In the Council's view, this is an appropriate way of relieving the shortage of organs, and it will be subjected below to ethical and constitutional evaluation. In conformity with the practice of the opt-out system in Spain and Austria, it is proposed in this connection that the relatives should be involved in so far as an objection on their part is material.

E PROPOSAL: A TWO-TIER MODEL COMBINING THE DECLARATION-BASED AND OPT-OUT SYSTEMS

1. Ethical aspects

The present Opinion does not deal with the entire field of organ transplantation in all its aspects, but concentrates on the question of how the shortage of post-mortem organ donations can be overcome or at least relieved, and proposes a two-tier model combining the declaration-based and opt-out systems. Accordingly, the following discussion is confined to the specific ethical aspects relevant to the issues here considered.

1. The shortage of post-mortem organ donations currently has the consequence that not all medically indicated organ transplants capable of preserving life or significantly improving quality of life can be carried out. In this situation, the adoption of measures likely at least to relieve the shortage is an ethical obligation. These include the proposal set out in this Opinion that the current opt-in system be replaced by a combination of elements of a declaration-based system and an opt-out system. After all, it appears unacceptable not to take advantage of opportunities for helping and healing such as organ transplantation and to withhold them from fellow human beings who have fallen ill – at least if there are no serious ethical objections to their development or application.
2. The ethical obligation to utilize the potential for helping and healing on the organizational and legal level has its counterpart, at individual level, in the duty to come to the aid of others, which results from the elementary precept of altruism or humanity. From this point of view, the willingness to donate organs after death should be regarded as a practical embodiment of the solidarity owed to a fellow hu-

man being threatened by a serious illness or death. This token of willingness to provide succour deserves recognition and high esteem.

For reasons of reverence for the deceased, his bodily integrity must be respected and his body must not be made an object of commerce. However, these considerations by no means imply that the body must be left untouched. Reverence is manifested primarily in relation to the memory of the deceased. It is bound up with the manner in which the living remember him and with the way in which they express their gratitude to him even after death. However, the circumstances in which organs are removed may in practice violate the dignity of the donor and also injure the feelings of his relatives. For this reason, all measures necessary for the purpose of organ retrieval must be taken with due regard for the medical duty of care, to ensure that the corpse can subsequently be handed over in a dignified state for disposal.

The right and wishes of the relatives to take their leave of the deceased appropriately and to see his body must be respected and carefully observed. The relatives should always be involved in the decision to remove organs. In particular, they must be given an opportunity of expressing their opinion. It is desirable if possible for them to give their consent to compliance with the wishes of the deceased or explicitly to confirm the deceased's presumed consent. If they refuse a planned organ removal, their objections should, in the case of next of kin (spouse, parents or children), be respected even if the deceased himself had no objection.

It should be possible for objections by next of kin to be overruled if the deceased explicitly consented during his lifetime to organ donation. Anything else would run counter to the declared wishes of the deceased and hence to his self-determination. However, it is inadvisable to insist on organ retrieval in the event of a categorical objection by the relatives. In order as far as possible to avoid the occurrence of such a situation, with which neither doctors nor relatives

ought to be confronted, anyone willing to donate organs after death should discuss this fully and in good time with his relatives or close friends. They should be involved in the intending donor's reflections on the situation and acknowledge, or at least be able to understand, his motives for opting to donate organs.

3. What is the relationship between consent to and refusal of post-mortem organ donation? Should they be regarded as moral possibilities of equal rank, to be chosen by each individual in accordance with his preference, or are there sufficient reasons for preferring one of the two alternatives?

a) On these questions, differing moral views collide. Some see organ donation as a test case of solidarity with other human beings and a "duty of love" to be expected from every individual; no one can in their view evade it for morally respectable reasons; an action dictated by the humanity that is the duty of all human beings cannot be left to the discretion of the individual. Others, however, insist that refusal to agree to organ donation can also constitute a morally justifiable decision. From this point of view, such a decision must not be discriminated against and must be seen as one that can be made for respectable reasons. In particular, concern for the relatives, who often experience the time immediately after the death of the deceased as extremely traumatic, can be a justifiable reason for not consenting to organ donation; the relatives, according to this view, cannot take their leave of the deceased in undisturbed fashion if this period is taken up by the medical procedures necessary for organ retrieval (artificial circulation in the body, surgical removal of the organs, and necessary after-treatment of the corpse).

b) As to the alternatives of a general duty of solidarity, on the one hand, and a decision taken freely at the individual's discretion, on the other, the fundamental principle of

all ethics and morality must be borne in mind. This principle is also of paramount importance with regard to the legitimization of organ donation. It is that the moral value of any act – irrespective of whether it is or is not strictly speaking an obligation – depends on its being performed voluntarily and not by coercion. Conversely, this principle also signifies that an expression of wishes concerning organ removal (consent or objection) documented during the lifetime of the deceased must be respected in order not to violate the deceased's right of self-determination. It follows that organ donation should preferably result from a free decision on the part of the person concerned. This decision does not have its counterpart in a legally enforceable claim by the recipient. For the recipient, the generous donation of an organ by someone unknown to him is instead a gift, which he can only receive and accept in gratitude and with confidence.

c) Just as, for the recipient of an organ donation, existential dependence on a donated organ and the character of the organ as a gift are not mutually exclusive, so, on the part of the donor, the moral obligation of humanity and altruism, on the one hand, and the voluntary nature of organ donation, on the other, are not antithetical. In view of the possibility of helping a fellow human being in the extreme distress of a serious illness effectively and with good prospects of success, refusal to donate organs cannot be a matter left entirely to the discretion of the individual. The individual should at least be called upon to render account to himself as to why he rejected this possibility after mature reflection. In so doing, he must not only consider that the inability to take advantage of the potential of transplant medicine due to the shortage of organs can have serious consequences for many people – in the extreme case, death – but should also reflect on how he himself would rate the possibilities afforded by transplant medicine if he were to find himself in the position not of a potential donor but of a possible organ recipient.

To the extent that transplant medicine opens up possibilities of disposal over the human body in ways that previously did not exist, it also confronts us with new challenges to our capacity for moral judgement and personal decision-making. In this connection, life and death are bedfellows as never before. After all, everyone knows that his own death – especially a premature death due to accident or incurable disease – makes it possible, by the donation of an organ, to help a fellow human being to overcome a severe impairment and to lead a newly gifted life both professionally and in the bosom of his family. Even if organ donation is not a moral obligation in the strict sense, the mere knowledge that this possibility of help may in certain circumstances exist presents a challenge to the exercise of one's personal judgement. Simply keeping at bay thoughts of one's own death or postponing a conscious decision for or against organ donation is not a satisfactory response on the human level. Instead, the mere possibility of helping to save other people's lives by consenting to organ donation constitutes an appeal to make a prompt and responsible judgement.

d) An important aid to arriving at a consistent judgement in accordance with one's wishes and preferences is contained in the Golden Rule (for instance, in the form "Do as you would be done by"); another is fictional role playing. Both invite one to an imagined exchange of places, in which each individual asks what he would expect from the others if he were to need their help. Existential familiarity with one's own situations of distress enables one to discover what one can do for a fellow human being in the same plight. Anyone who finds himself, as a result of the vicissitudes of his life, in a position in which he is called upon to help others should be willing to render this help, just as, conversely, he would expect to receive help from them in a similar situation.

A responsible, thoroughly considered, conscience-based decision is essential precisely in the sensitive sphere in which

the death of one person and newly acquired prospects of life for another are intimately bound up with each other. If someone, as a potential organ recipient, hopes to receive a gift through the magnanimity of a stranger, he should, in the converse situation, be prepared to make his organs available for the sake of the lives of others. A refusal to donate organs remains consistent only if it takes account of both sides affected by such a decision. The refusal becomes unfair if it is accompanied by the secret hope of being able, in the event of a serious illness, to make unilateral use of the possibilities of transplant medicine by relying on the generosity of others. Even so, in the case of both indecision and refusal, no individual should be placed at a disadvantage in the matter of access to health care.

e) The starting point for the considerations set forth in this section was the question: what is the relationship between consent to and refusal of post-mortem organ donation? The answer is clear: willingness to donate organs after death is the objectively preferable ethical alternative. Yet it remains the case that consent to organ donation after death is a generous gift and that, for this reason, no one must be compelled, either legally or morally, to consent to it. There are respectable motives for refusing organ donation. In addition to the wish for relatives and friends to be able to take their leave of the deceased in peace – although this is in fact also perfectly possible where organs are donated – a particularly important part is played in this connection by the "brain death debate". Even if a consensus was reached in the process of adoption of the Transplant Law, and even if the scientific issues surrounding brain death have been substantially resolved, the circumstance must be respected that quite a few people give more credence to the apparent fact that a brain-dead person still exhibits movements and reactions than to scientific statements about the irreversibility of brain death.

4. From the ethical point of view, the legal provisions governing organ donation should strike a balance between two competing objectives. On the one hand, they should embody the principle that the free and informed consent of the donor and his relatives is the preferred ethical basis for legitimization of transplant medicine. On the other hand, they should make fuller use of the public's substantial willingness to donate organs than has hitherto been possible. If legislation incorporating elements of the opt-out system is contemplated on account of Germany's sobering experience with the wide opt-in system, these must be assessed in ethical terms in accordance with the extent to which they are consistent with the voluntary principle. The assumption that society has a general right of disposal over the human body – which is the ultimate implication of a social obligation basis for organ removal – remains irreconcilable, at all events, with the principle of self-determination that prevails in our culture. A combination of elements of a declaration-based system with aspects of an opt-out system appears to be the best approach to satisfying the ethical requirements described here. The State would then be obliged to ensure that citizens are systematically invited (for instance, when a health card is issued or on application for a driving licence) to make a personal declaration as to whether they are prepared to donate organs. The law should also stipulate which documents (for example, the health insurance card or health card, organ donor card or a central register) should be considered for recording the personal declaration and should therefore always be consulted by hospital staff.

The solution proposed here is based on the view that the donor's freely given consent is the preferred ethical basis for legitimizing organ transplantation. In such a context, the complementary application of an opt-out system is ethically acceptable. Although the obligatory exercise of the donor's right of self-determination is then reduced to a minimum – that is, that neither he himself nor his relatives should have

registered an objection – this is acceptable by virtue of the prior procedure whereby as many explicit declarations of consent to organ donation as possible are generated, in conjunction with the State's obligation to provide detailed and sustained information about the opt-out system rather than secretly relying on public ignorance.

It is admittedly possible for a potential donor, even if he is familiar with the system, not to register an objection, for instance owing to lack of interest or indecision, so that he does not in practice agree to the donation of organs. However, in view of the legitimate objective of taking as much advantage as is ethically acceptable of the possibility of helping and healing by means of an organ transplant, it is legitimate for the law to deem such indecision to be tantamount to the setting aside of objections to organ removal and therefore to assign priority to the possible saving of life or reduction of suffering.

5. Such an approach is at the same time an appropriate response to more thoroughgoing demands for financial incentives to donate organs, as have been expressed with a view to the elimination of practical disadvantages of the current opt-in system. It is not ethically desirable for the voluntary nature of organ donation to be called into question by financial incentives. The principle that the human body must not be treated as a marketable commodity protects an area of individual freedom in which a personal decision in favour of organ donation can be taken without the pressure of material considerations. The culture of the voluntary exercise of solidarity is one of society's most important moral resources. It is not desirable for all interpersonal relationships, especially in the sensitive field of life and death, to be subjected to the logic of the market and determined by the rules of economic processes of exchange.

2. Constitutional permissibility

2.1. Affected fundamental rights

A donor's fundamental rights are the principal criterion for assessment of State regulation of post-mortem organ donation, because the protection afforded by several of these fundamental rights extends to situations even after a person's death. The State's obligation under Article 1(1) of the Basic Law (German Constitution) to respect the dignity of every individual does not end with the individual's death, but also extends to the treatment of his corpse. The right of self-determination derived from the first sentence of Article 2(1) in conjunction with Article 1(1) of the Basic Law guarantees the individual the ability to make provisions in the sphere of his personal life that will take effect only after his death. In addition, Article 4(1) and (2) of the Basic Law grants the individual the right to adduce his own faith or *Weltanschauung* in deciding what is to be done with his body after his death.

The opt-out system encroaches on the right of self-determination in a number of respects. The fact that a person's body can be appropriated for organ donation without his consent if he has not registered an explicit objection already constitutes one encroachment. Another limitation on self-determination is that the onus of making a relevant declaration is placed on those who do not wish to be organ donors but instead to have the integrity of their bodies preserved after death. The introduction of an invitation to declare whether or not one wishes to donate organs affects first and foremost the fundamental right of self-determination, as the individual is compelled – possibly against his will – to concern himself with matters of organ donation and his own death. In addition, the freedom of faith and *Weltanschauung* would be affected if the declaration-based system ultimately had the effect of forcing people to disclose their religious and philosophical convictions.

Not only the fundamental rights of potential organ donors but possibly also those of relatives of deceased persons may be affected. For instance, the existence of an encroachment on the freedom of religion and *Weltanschauung* could be assumed if the relatives were prohibited by State regulations from disposing of a corpse in accordance with the rules and rites of their religion. The relatives' right of self-determination could be affected if they were expected to make a decision, in place of the deceased, for or against the removal of organs from his body.

However, the Constitution protects not only the rights of potential organ donors and their relatives, but also the interests of those who depend on a donor organ for their survival or the treatment of their illness. Although no one can derive a subjective claim in law against the State to receive a donor organ from his fundamental rights to life and bodily integrity, the fundamental rights are values contained intrinsically in the Constitution, and the protection of these rights is an objective obligation of the State – whether or not the individual can make a claim in law for them. For this reason, the objective character of the provision laid down in the first sentence of Article 2(2) of the Basic Law obliges the State to assume a protective posture in relation to the life of every individual. Yet the Constitution does not stipulate the form which this duty of protection must take; that remains substantially a legislative decision. It nevertheless follows from the obligation to protect life and bodily integrity that the State must at all events not without adequate reason stand in the way of possibilities of medical treatment. This obligation must also be taken into account with regard to the provisions governing organ donation.

2.2. Considerations

2.2.1. Human dignity and freedom of faith

It is generally agreed that the opt-out system does not constitute a violation of human dignity, if only because the individual retains the right to decide whether or not he wishes to make himself available as a donor after his death. In this case, there is absolutely no need to consider whether it would constitute an instance of instrumentalization that violates human dignity if a person had to accept the fact, without the possibility of refusal, that organs would be taken from his body after death in order to save other people's lives. If one's personal decision takes absolute priority, at any rate, no such instrumentalization exists. Nor is the freedom of faith and *Weltanschauung* infringed. Everyone is free to object to organ removal, or not to register an objection, in accordance with his personal convictions. Again, since no reason need be given for opting out, no one must disclose the religious or philosophical reasons for his refusal. The freedom of faith or *Weltanschauung* is likewise not violated if the individual is required by law to declare whether or not he wishes to make himself available as an organ donor. Since no justification for one's declaration is demanded, it does not involve the divulging of information about one's faith or *Weltanschauung*.

2.2.2. Self-determination

The decisive element in the constitutional assessment of a demand under the opt-out system to make a declaration on organ donation is whether the encroachment on self-determination inherent in such a system is permissible. Apart from a certain core area of self-determination that cannot be relinquished, assignable to the sphere of human dignity, the right of self-determination pursuant to Article 2(1) of the Basic Law is explicitly subject to limitation by legislation. This means that the right of self-determination can be restricted by a law, which is a part of

the constitutional order. Such restrictions already apply to the arrangements one may wish to make for the disposal of one's body after death. The right of self-determination after death is limited not only to a significant extent by the funeral laws of the individual Federal Länder, in that the place of disposal and other ways of dealing with human corpses are not left to the discretion of the deceased and his relatives, but also by the current legislation governing post-mortem examinations and protection from infection. In these last two fields of law, there is not even a right to object to what may be a substantial encroachment on bodily integrity if a post-mortem or other examination is deemed necessary in the interests of the investigation of criminal acts or to protect others from infectious diseases.

Nor is a restriction of self-determination accruing from the obligation to help others alien to German law. For instance, Section 323c of the Criminal Code provides that it is a punishable offence not to render assistance to another person in distress if it is reasonable to do so in the circumstances of the individual case. According to the case law of the Federal Court of Justice, the requirement to render assistance is deemed unreasonable only if it involves appreciable danger to the person rendering assistance himself.³² An obligation to render assistance is also stipulated in Section 34 of the Criminal Code, on justifying emergency situations: in this case, an encroachment on the individual's sphere of interest is required to be tolerated if it is necessary in order to safeguard another person's much more important interest.

It is true that these provisions, whose constitutionality is unquestioned, are not directly applicable to the situation of post-mortem organ donation.³³ However, they do demonstrate the extent of the freedom granted by the Basic Law to the State

³² BGHSt [Federal Court of Justice] 36, 166.

³³ An obligation on the individual to donate his organs after death cannot be derived from Section 323c of the Criminal Code if only because, according to that provision, only living individuals can render themselves liable to a penalty. Under the emergency-situation provisions of Section 34 of the Criminal Code, post-mortem organ removal without the necessary consent

to demand that the individual set aside interests of his own for the purpose of helping others in need. Yet these provisions should not be adduced as a model for justifying the permissibility of the opt-out system. While it may be doubted whether an obligation to donate organs after death is genuinely comparable with the cases mentioned above of obligation to render assistance to third parties, there are also other arguments against this approach. In particular, however, the opt-out system should not be underlain by an obligation to render assistance, possibly enforceable even against the wishes of the person concerned, but instead by presumed consent to this assistance. It is only on the assumption of presumed consent that it is understandable why unconditional precedence is accorded, in the opt-out system, to the declared wishes of potential organ donors. The statutory presumption of consent to assistance can be invalidated at any time simply by registering an objection without the need to give reasons; this is not the case where the rendering of assistance is compulsory.

The presumption of consent to post-mortem organ donation suggests itself owing to the public's high declared willingness to donate. When incorporated in the opt-out system, it constitutes only a minor limitation of the self-determination of the individual, on whom the requirement to make a declaration is imposed. However, a possible consequence of the opt-out system in practice is that organs may be removed from a person after his death against his wishes, because he failed to express those wishes. But if suitable measures are adopted to ensure that as many members of the public as possible make an explicit declaration as to whether or not they wish to be organ donors, and if the public are also sufficiently informed that failure to opt out may result in organ removal, then it is perfectly justifiable for

of the donor or his relatives could be justified at most if it served the purpose of avoiding a present danger to the health of others that could not otherwise be avoided. A consensus does not exist on whether this condition is satisfied if the organs are removed not for a specific patient but instead, as is usual, placed at the disposal of Eurotransplant for allocation.

the law to deem the wishes of those concerned to be a legitimate basis for organ removal provided that a wish to the contrary has not been declared.

The invitation to make a declaration on organ donation, coupled with information on the opt-out system, compels people to concern themselves with the subject of organ transplantation and hence also to confront the fact of their own death. This can be regarded as an encroachment on the right of self-determination, which, after all, includes the right not to concern oneself with something and not to make a decision. However, this encroachment is limited and if anything less significant than the encroachments otherwise imposed on the individual by the constitutional order in the public interest. The same applies to the obligation imposed by an opt-out system to make an explicit declaration if one does not wish to be an organ donor. In a terse formulation, the Federal Constitutional Court has ruled that it is “not evident” that potential organ donors “already experience an infringement of their fundamental rights by virtue of the fact that they must declare an objection in order to avoid the alleged infringements of their fundamental rights [namely, infringement of their dignity and right of self-determination].”³⁴ In the light of this decision, it can also not be deemed unconstitutional for consent to be presumed, and sometimes to have been actively given, under the opt-out system if potential organ donors have not registered an objection. It is perfectly justifiable for the law to accept the possibility that, in individual cases, failure to opt out may not imply consent but be based on ignorance or lack of interest, provided that it is ensured that the public are sufficiently informed about the consequences of not objecting. The encroachment on the bodily integrity of the deceased that is inherent in the opt-out system is justified by the higher-level objects of legal protection constituted by the preservation of patients' lives and health.

³⁴ BVerfG [Federal Constitutional Court] (First Chamber of the First Senate), NJW 1999: 3403, 3404.

According to the principle of proportionality, the opt-out system is permissible only if it is appropriate for achieving the objective in view – that is, increasing the number of available organs. Notwithstanding the difficulty of forecasting, this condition is likely to be satisfied. Nor can any less stringent but equally effective means of achieving this objective than the opt-out system be envisaged. In particular, experience in Germany shows that public education and appeals to donate organs do not by themselves suffice to meet the demand for organs.

Again, the combination of the opt-out system with an invitation to make a declaration on organ donation, as proposed here, constitutes less of an encroachment than the opt-out system alone. An alternative approach to increasing the number of transplants without curtailment of the right of self-determination would probably have to be based on appreciable financial incentives.³⁵ However, such an approach would be tantamount to relinquishing the altruism of organ donation, which is an important social good. Such relinquishment cannot be regarded as a less stringent means of increasing the number of available organs than the opt-out system.³⁶

Lastly, the onus of declaration imposed on the individual with a view to establishing who can be considered for organ donation must take a procedural form that minimizes the associated encroachment on the right of self-determination. This implies that people must be able to document their decisions quickly and without complication, that decisions once taken can be revised, that there is no compulsion to justify one's decision, and that sufficient time for reflection is allowed before making a declaration. In particular, however, an essential requirement is for the State to ensure that the public are fully informed about the significance of the opt-out system – that is to say, that if the decision is left open or deferred, consent to organ donation will

be presumed, and that anyone has the right to counter this presumption by opting out. The State should not speculate that the supply of organs will increase because the public are left unaware of the legal consequences of failure to opt out.

Relatives too have an interest worthy of protection in contributing to the decision on what is to be done with the deceased's body. This interest should be allowed for by enabling them too to refuse consent for organ removal (wide opt-out system). Subject to this condition, it is not evident that the fundamental rights of the relatives would be affected in a way that might call into question the constitutional permissibility of the opt-out system.

3. Summary

1. The basis of the ethical and constitutional assessment is that no system governing the removal of organs may dispense with the principle of voluntary organ donation. Organ donation must remain a gift free of either legal or moral coercion. The willingness to donate organs may be recognized and encouraged. However, if a person is not prepared to be an organ donor, this too must be accepted without reservation and without disadvantages to the person concerned. This principle could best be observed by making post-mortem organ removal dependent on the donor's explicit consent.
2. Encroachments on the right of self-determination, such as those involved in a declaration-based system in which people are called upon to make a personal decision, are both ethically and constitutionally acceptable. Organ donation is an act of solidarity and altruism that saves lives. Although no one is compelled to undertake such an act, there is no good reason for anyone not to respond to the appeal at least to consider whether one is willing to donate.

³⁵ Breyer et al. 2006: 125 ff.

³⁶ On the other hand, the introduction of the opt-out system could remove any vestige of justification from social demands for qualification of the exclusion of the profit motive from organ donation.

Such an appeal admittedly has implications for self-determination, because it forces one to confront the question of possible organ donation. However, if it remains possible not to commit oneself, there is in practice no compulsion to make a decision or to express a preference. Hence the limitation of the right of self-determination inherent in the appeal is slight. On balance, the legitimate aim of increasing the number of available organs deserves priority. The declaration-based system is a proportionate means whereby the State can contribute to the achievement of this aim within its field of competence and discretion.

3. The opt-out system is ethically and constitutionally acceptable at least when combined with elements of a declaration-based system. The aim must be to ensure that organ removal can be supported in as many cases as possible by explicit consent. Under the opt-out system, while organ removal against the wishes of the potential donor is not allowed, it is permissible in the absence of such a decision. This system violates neither human dignity nor the freedom of faith or *Weltanschauung*, because it does not affect the core of the right to decide for oneself whether or not one wishes to be an organ donor, and because it does not force anyone to disclose the reasons for this choice. However, the opt-out system does encroach on self-determination, because it places the onus of declaring an objection on those who do not wish to donate. Yet this encroachment does not extend beyond the bounds set by the Constitution for legislation involving possible restrictions of self-determination. After all, it not only serves a legitimate public interest, but also complies with a duty of the State to protect human life – namely, the duty to improve the supply of donor organs for patients. This encroachment is ultimately a means of achieving this goal that is permissible in accordance with the principle of proportionality.

In this connection, the justification for organ removal under the opt-out system lies not in a solidarity-based obligation to donate, but – provided that an adequate basis for presumption is created by appropriate measures – in the presumed consent of the potential donor. An obligation to donate organs cannot be justified; for this reason, there can also be no assumption of a right of the community to have recourse to the organs of deceased persons for transplant patients, where such a right might override the wishes of those concerned. Conversely, a statutory presumption of consent to organ donation can be justified – because, following thorough public education about the opt-out system, there is every reason to assume that any serious refusal would be expressed in an opt-out. Furthermore, consent can be expected both on the practical and on the normative level. In practical terms, consent may be expected because the public's declared willingness to donate organs is actually very high; and it may be anticipated from the normative point of view because most people would wish where necessary to have access themselves to a donor organ, and because they accept the Golden Rule's moral norm that benefits that one expects or at least hopes for from others should be paralleled by one's own actions.

The legitimacy of the opt-out system depends on the public's not being left uninformed of the consequences of failure to register an objection. In addition, the opt-out system should be accompanied by provisions directed towards replacing presumed by actual consent to organ donation. For this purpose, there should be a general invitation to individuals to declare their availability or non-availability for organ donation. However, it should also be possible to declare that one prefers not to make a decision and instead to accept the statutory solution. An opt-out limited to certain organs must also be possible.

4. The model proposed in this Opinion should be introduced in stages in the transitional phase. Before the opt-out system as such can take effect, the public must be sufficiently informed of the consequences of failure to opt out.

F RECOMMENDATIONS

The National Ethics Council's recommendations are as follows:

1. Appropriate legislation should be passed to ensure that hospitals comply to a greater extent than hitherto with their obligation to report potential post-mortem organ donors.
2. All costs incurred by hospitals in connection with the reporting and treatment of potential organ donors (even where organs are not ultimately removed) should be adequately reimbursed.
3. A two-tier model should be introduced by law, combining a declaration-based system with an opt-out system in relation to the permissibility of organ removal after death as follows:
 - a) The State would be obliged to ensure that the public
 - >> are called upon by a formal procedure to make a personal declaration as to whether they consent or object to organ donation (possibly with respect to specific organs); and
 - >> are informed that organ removal is legal in the absence of a declaration provided that the relatives do not object.
 - b) Subject to the premises set out in item (a), organ removal should automatically be permissible if there is no indication of an objection, unless the deceased's relatives refuse consent. However, before organ removal, all reasonable efforts must be made to establish the wishes of the deceased or, where applicable, of the relatives.
 - c) In addition, measures must be taken to ensure adequate public information on the consequences of failure to opt out of organ removal.

d) The model proposed here should be introduced in stages in the transitional phase. Before the opt-out system as such can take effect, the public must be adequately informed of the consequences of failure to opt out.

e) Possible ways of documenting the declaration mentioned in item (a), in addition to the organ donor card, are the health insurance card or health card, or a central register.

References

Breyer, F., et al. (2006). Organmangel. Ist der Tod auf der Warteliste unvermeidbar? Berlin.

Deutsche Stiftung Organtransplantation (2006). Organspende und Transplantation in Deutschland. Bundesweiter Jahresbericht 2005. Neulsenburg.

Deutsche Stiftung Organtransplantation (2007). Erstmals über 4000 Menschen durch Organspende gerettet – Anzahl der Transplantationen im Jahr 2006 auf Höchststand. Press release of 26 January 2007. <http://www.dso.de> (accessed on 10 April 2007).

Eurotransplant International Foundation (2006). Annual Report 2005. Leiden.

Robert-Koch-Institut/Statistisches Bundesamt (2003). Organtransplantation und Organspende. Gesundheitsberichterstattung des Bundes, Heft 17.

Schulz, K.-H., et al. (2002). Lebensqualität nach Organtransplantation. Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz 45: 782–794.

Wissenschaftlicher Beirat der Bundesärztekammer (1998). Richtlinien zur Feststellung des Hirntodes. Deutsches Ärzteblatt 95: A 1861–1868.

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