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Opinion no. 6/2003 –
On the regulation of living donation in
the transplantation law

Approved by the Commission
on 17 November 2003

Preface

The transplantation of organs, tissues or cells from living donors seems to be growing in importance compared with transplants of body parts from brain-dead patients. In addition to the kidney – the organ most frequently obtained from living donors – living donation is now possible for an increasing number of organs or organ parts: portions of the liver and lung, small intestine, pancreas, etc., as well as bone marrow, bone material and blood stem cells. Moreover, the prospects of successful treatment are better with living donor grafts than with organs from brain-dead donors. The increase in living donor transplants can also be attributed to the emergence of new applications and doubtless also to the decline in the availability of organs from brain-dead patients.

These developments have been accompanied by a normative reassessment of living donation, not only within the legal framework in various countries but also as regards moral evaluations. This shift in values is also reflected by the Swiss Transplantation Law, which represents the immediate occasion for the publication of the present Opinion by the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE). Rather than being regarded as a fallback in the absence of cadaveric organs (i.e. merely a symptom of the “organ shortage”), living organ donation is now considered to be a treatment option in its own right. At the same time, donors are increasingly held to be capable of making autonomous decisions concerning the gift of a non-essential organ, organ part or tissue. This raises a whole range of novel ethical issues, both for transplantation medicine itself and for the legal regulation of this field. These questions are of a different character to the problems typically associated with the recovery of organs from brain-dead patients (e.g. the status of brain death, arrangements for donation, communication with relatives), and they cannot be understood by adopting an approach that focuses on the brain death situation.

The specific questions arising in connection with living donation concern the risks and restrictions that are accepted by a donor for the sake of another person. They relate to decision-making processes and the institutional arrangements that are to be made for the provision of psychosocial support to potential donors, in order to ensure the quality of decisions. However, the questions also concern the cultural patterns and social expectations that are inevitably associated with this procedure: being a living donor means sharing one's own body with others. On the one hand, this sharing is an act of solidarity and compassionate responsibility; on the other, it is an act of self-division, sharing one's own physical substance. In the latter sense and in relation to this responsibility, the act of sharing resonates with culturally influenced patterns of body perception and self-image, which may perhaps explain the preponderance of women among donors. But living donation is becoming an increasingly widespread standard medical practice, and this development is itself contributing to a

cultural shift in our conception of the human body. Although it may remain clear in legal terms that one's body is one's own exclusive property, from a moral perspective the practice of sharing and the body's divisibility create new scope for acts of solidarity and charity. This creates new hopes for people with life-threatening illnesses and new kinds of responsibility on the part of potential donors; within relationships and families, however, it may also give rise to new kinds of dependence.

In the spring of 2003, the NEK-CNE was asked to prepare an Opinion on whether living liver donation should be financed by social health insurers. In view of the increased risks for donors, this is a controversial issue. In the course of these investigations, which led the Commission in October 2003 to express its support for reimbursement of the costs of this procedure by social health insurers (cf. Appendix, Opinion no. 5/2003), the NEK-CNE examined the section on living donation in the draft Transplantation Law. This legislation had been prepared before the establishment of the NEK-CNE. The Commission proposed a series of amendments for the parliamentary deliberations. In the view of the NEK-CNE, the draft Law of 12 September 2001 does not adequately address the complexities of living donation. In particular, it fails to provide adequate protection for donors, who may themselves be prepared to accept major risks in order to cure relatives and friends. Appropriate regulations could be included in the Law, or introduced in an associated Ordinance. The Commission's recommendations have previously been issued as separate publications – a concise version, approved on 3 July 2003, and Opinion no. 6/2003, approved on 17 November 2003. The latter document forms the central part (Section 5) of the present booklet. Certain changes requested by the NEK-CNE were accepted by the National Council when the Transplantation Law was adopted.

This booklet also includes a number of background sections designed to promote understanding of the problems of living donation. An account of developments in transplantation medicine is given by Gilbert Thiel, a pioneer in the field of kidney transplantation in Switzerland. The Commission's Opinion is preceded by a summary of the state of the ethical debate on living donation, written by the theologian Andrea Arz de Falco. Following the Opinion, excerpts are reproduced from three interviews with individuals directly concerned – a donor and two recipients; these examples, which make no claim to be representative, provide a vivid insight into the challenges, emotional intensity and human complexities involved in living donation. The final part of the booklet comprises interviews with the transplantation immunologist Jürg Steiger (on clinical experience with living kidney donation) and the psychosomatic physician Alexander Kiss (on his experience in providing psychosocial care for liver and kidney donors). The booklet concludes with a brief overview of the international legal situation and trends. This section draws essentially on the work of Thomas Gutmann and Ulrich Schroth from the Faculty of Law at the University of Munich.

I would like to express my sincere thanks to all those involved in the preparation of this publication: to Professor Gilbert Thiel, for writing the introductory medical section; to Dr Andrea Arz de Falco, for summarizing the state of the ethical debate; to Professor Alexander Kiss, for describing the care received by donors; to Professor Jürg

Steiger, Dr Ulrike Kostka, Professor Gilles Mentha, Professor Pierre-Alain Clavien and Dr Eberhard Renner for acting as experts. The theologian Dr Ruth Baumann-Hölzle wrote a detailed report, which provided an important stimulus for the Commission's deliberations. Our consideration of living liver donation was greatly assisted by the documentation and expert contributions provided by Dr Guillermo Aréstegui, Dr Felix Gurtner and Dr Stefan Koller. But I am also particularly grateful to the three individuals directly concerned for their openness in sharing with us their extremely valuable experiences. I would also thank Franziska Genitsch and Rouven Porz for transcribing these interviews. The preparation and production of the various versions of this Opinion would not have been possible without the support of NEK-CNE staff members Georg Amstutz and Csongor Kozma, who also organized the numerous meetings and discussions that were required. I also wish to thank all of my colleagues on the Commission for their awareness of the broader context of the dilemmas arising in medical ethics, for their patience and attention to detail, and for their commitment to the task at hand.

Unfortunately, owing to budgetary cuts, it was not possible for this booklet to be produced in a professionally laid out and printed format.

Christoph Rehmann-Sutter, Chairman of the NEK-CNE

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Opinion no. 5/03

Living-donor partial liver transplantation: the question of financing

1 – Overview

Living donation is playing an increasingly important role in transplantation medicine. Not only the kidney, but also parts of the liver, lung and small intestine, as well as bone marrow and other tissues, can now be obtained from living donors and successfully transplanted; the risks involved are low or, if more substantial, possibly still acceptable. The ethical issues identified in this field by the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) are here presented in context.

The Commission's Opinion no. 6/2003 (November 2003) "On the regulation of living donation" forms the central part of this booklet. This Opinion, which was prepared in connection with the parliamentary deliberations on the Transplantation Law, includes a series of recommendations for amendments to legislation.¹

The NEK-CNE recommends that additional provisions concerning living donation should be included in the Transplantation Law and associated Ordinances. It believes that the Law should contain additional regulations on the protection of donors, provide better support for donors' decision-making and assure the provision of appropriate care. For these purposes, it proposes that the federal government should establish a national body serving ombuds and advisory functions for all the parties involved. In order to provide a foundation for risk evaluation, a living donor registry should be maintained and assessed.

In addition to reviews of medical developments and the international legal situation in this area, this booklet includes background information from the perspective of donors and recipients, and a description of psychosocial care for donors.

¹ A separate Opinion prepared in parallel by the NEK-CNE on the financing of living liver donation has been included in an Appendix.

2 – Living donation: the medical situation in Switzerland at the end of 2003

Gilbert Thiel (University of Basel)

Essentially, there are two different scenarios: living donation for transplantation purposes can involve organs (the kidney or parts of the liver, lung, pancreas or small intestine) or stem cells (harvested from bone marrow or peripheral blood following stimulation). While the former have to be implanted surgically, the latter can be administered by intravenous infusion.

Switzerland's first living organ donation (a kidney transplanted from mother to son) took place in Basel on 7 February 1966. This was followed 5 months later by a second procedure, performed in Zurich. Living donation was subsequently banned at Zurich University Hospital on ethical grounds by Professor A. Senning, who held the Chair in Surgery at that time. As a cardiac surgeon, he was not himself seriously affected by this ban, since the question of living heart donation will never arise. However, Senning's prohibition was respected for over 20 years – also by his successor, Professor F. Largiadèr. At the other Swiss centres, especially in Basel, living donor kidney transplantation was pursued without interruption, although these procedures accounted for only about 5% of the total and were thus a marginal phenomenon alongside the 95% involving cadaveric organs.

The situation changed at the end of the 1980s as the shortage of cadaveric organs became more acute, and in 1990 an international congress on the ethics of organ transplantation, attended by professional ethicists, led to a re-evaluation. One of the resolutions adopted was that "live donor kidney transplantation between spouses and other emotionally related persons is ethically acceptable". Conversely, the concept of brain death and hence also cadaveric organ transplantation came under pressure over the following years.

The 1990s were a decade that saw various new ideas taking root in the area of living donation in Switzerland. In 1991, a programme was launched and successfully developed in Basel for emotionally (non-biologically) related kidney donors (e.g. a partner, old school friend or father-in-law). Living donation was further boosted by the surprising findings of a major US statistical study published by P. Terasaki et al. in 1995. This showed that living kidney donation between spouses produces substantially better outcomes than cadaveric kidneys (results as good as in cases where there is a 50% match, e.g. parent-to-child donation). The procedure was thus supported by a quantitative argument (shortage of cadaveric kidneys) and a qualitative argument (superior results). An additional argument emerged: there was a growing realization that because living kidney donation can be planned

and the onset of end-stage renal failure can be predicted years in advance, transplantation can be carried out instead of dialysis (i.e. as a pre-emptive measure). It became increasingly clear that pre-emptive transplantation produces the best results in many respects – life expectancy, graft survival, continued employment, quality of life for all family members, and cost savings due to the avoidance of dialysis and disability benefits.

In 1998, a living donor kidney was removed for the first time in Switzerland by laparoscopy (an image-guided procedure using narrow instruments inserted through small incisions; performed in Basel), and in Geneva a living donor small intestine was transplanted for the first time. In 1999, Switzerland's first living donor partial liver transplantation was carried out in Geneva. The same year saw the first double kidney transplantation between two married couples (a procedure known as crossover transplantation or paired renal exchange), performed in Basel. In each of these couples, one of the partners was undergoing dialysis and direct donation from the healthy partner to the patient within the couple was not possible on account of blood group incompatibility. The crossover arrangement enabled both couples to be helped.

In this country, the number of brain-dead donors continued to decline after the turn of the millennium (from 101 in 1999 to 70 in 2002). In contrast, living kidney donation is becoming increasingly popular at all Swiss centres. In 2002, as a result of these contrasting trends, the total number of living kidney donors exceeded that of brain-dead donors for the first time (73 vs 70).

In 2003, living liver donation suffered a sharp decline – not because of poor results or a lack of potential donors, but for financial reasons. The SVK (Swiss health insurers' umbrella association) decided to discontinue the financing of living liver donation. For the rest of the year, until the time of writing (25 November 2003), no further operations of this type were performed at the two Swiss centres that had previously carried out 22 living donor liver transplantations (13 in Geneva, 9 in Zurich). These figures do not include one other living liver donation in Lausanne, where however no further procedures are planned (i.e. a total of 23 living donor liver transplantations have been performed in Switzerland to date).

The consequences of a moratorium of this kind can be seen from a simple calculation. In Switzerland, based on the figures for 2002, the annual brain-death donation rate is 10 per million population (pmp). Each year, about 20 patients pmp develop end-stage liver disease, i.e. about twice as many livers are required as are available. The problem would be soluble if all cadaveric livers could be divided into two grafts (split-liver transplantation). However, for anatomical reasons, division yields a larger right and a smaller left lobe. The smaller portion is adequate for children and those of short stature, but not for adults of normal height; in addition, only some cadaveric livers are suitable for division. Thus, in practice, if living liver donation is not an option, a third of all patients who develop end-stage liver disease have no chance of receiving a graft. The list of those waiting for a liver transplant does not, however, grow like the kidney transplant waiting

list, as those with liver disease tend to die before any accumulation can occur. Living donation of the pancreas or lung has yet to be introduced in Switzerland.

The first bone marrow transplantation to be attempted in Switzerland – albeit without success – took place in Basel on 4 April 1969. After a lengthy interval, a bone marrow transplantation programme was launched at the same centre in 1973, although the success rate was initially unsatisfactory until the introduction of cyclosporin A in 1980. On 8 April 1991, haemopoietic stem cell transplantation was first performed in Switzerland (Basel) instead of bone marrow transplantation, which had previously been the standard procedure. In both cases, haemopoietic stem cells are transplanted, but with the new procedure they are collected from peripheral blood following stimulation with a growth factor. The removal of stem cells from umbilical cord blood is also a “living donation” procedure; in this case, consent is required not from the newborn – the actual donor – but from the mother.

The most frequently performed type of tissue transplantation in Switzerland is corneal grafting (approx. 500 per year). As this involves exclusively cadaveric corneas, it clearly does not come under the heading of living donation. Grafting of skin from living donors is a fairly common clinical procedure, but in this case tissue is removed from a healthy area of the patient's own body (autologous graft). The same applies to bone, tendons, arteries, veins, fatty tissue and other types of tissue.

Transplantation of tissue formed *in vitro* (sometimes *in vivo*) as a method of replacing or repairing defective tissue (skin, cartilage, heart muscle, skeletal muscle, liver, peripheral nerves, retina, etc.) is still largely at the experimental stage. Such methods are frequently, but not always, based on the use of autologous stem cells. If an artificial scaffold is used to promote differentiation, growth and the desired three-dimensional structure of cellular tissue (e.g. releasing specific growth factors in the appropriate sequence), the concepts of stem cell transplantation and tissue engineering begin to shade into each other. With the exception of haemopoietic stem cell transplantation, and perhaps also the transplantation of tissue-engineered skin and cartilage, medical “repair” methods that could be classified as living donation based on autologous (stem) cells still have a long way to go before they can be applied in clinical practice; however, they do hold out great promise for the future.

At present, the two main types of living donor solid organ transplantation (kidney and liver) face a number of problems – some common to both, others unique to each.

In patients with kidney disease, living donor organ transplantation is never the only life-saving option, as long-term dialysis is available as an alternative. Quality of life is, however, considerably better with a transplant (as confirmed by numerous studies), and patients have to wait for a period of years to receive a cadaveric kidney. De facto, given the existing shortage of cadaveric organs, the benefits of pre-emptive transplantation (including the associated increase in life expectancy)

can only be obtained with the aid of living donation, and dialysis cannot be used indefinitely to defer the point at which pre-emptive transplantation would be possible or necessary without sacrificing these benefits. Living kidney donation may be motivated by various factors, ranging from intense feelings of love for one's own child or partner, through a sense that one is obliged to help a close relative or friend, to the realization that this would be the best way of improving one's own quality of life (i.e. donation that is not "purely" altruistic). This list is not exhaustive. In the case of living liver donation, the donor's motives are not different, but there is greater pressure given the lack of an alternative corresponding to chronic dialysis.

A problem arising with both procedures is the fact that many donors (especially those whose decision to donate is almost immediate) often view the situation through rose-coloured spectacles, and do not wish to acknowledge the risks involved for themselves and the recipient. It is the responsibility of the transplantation centre and the external counsellor to bring prospective donors down to earth by confronting them with the actual incidence of complications (in donors and recipients). For this purpose, however, the relevant statistics need to be available.

Surprisingly and regrettably, a Swiss Kidney Transplantation Registry comprising records of graft survival and recipient mortality is only in the initial stages of development, and results cannot yet be accessed. Data on Swiss kidney transplant recipients is included in the Collaborative Transplant Study (CTS) at the University of Heidelberg, but the study's directors are not authorized to disclose overall results for Switzerland. Worldwide, the CTS results indicate 1-year and 5-year graft survival rates of 92% and 80% respectively, in each case about 5% better than with cadaveric kidneys. At present, it is not possible for a Swiss transplant coordinator to examine the current success rates in Switzerland. In contrast, a national registry monitoring health and complication rates in living kidney donors at 2-year intervals has been in existence for the past 10 years – the Swiss Organ Living Donor Health Registry (SOL-DHR). Since 1993, 631 living kidney donors have been included and the total is increasing month by month. Seven years after donation, hypertension is observed in 35% of kidney donors. Although the incidence is not greater than in an age-matched Swiss control group, it is particularly important to treat elevated blood pressure in single-kidney patients in order to prevent damage to the remaining kidney (indicated by urinary albumin excretion). After 7 years, 9% of kidney donors exhibit albuminuria. The SOL-DHR alerts donors and their GP if signs of kidney damage emerge. The provision of aftercare for living kidney donors is considered to be a medical obligation. Worldwide, 1 in 3000 kidney donors have died as a result of the procedure, representing a perioperative mortality of approx. 0.04%. Of the total of 631 kidney donors included in the Swiss registry, 6 have died, but none of these deaths was attributable to the kidney donation (2 malignant tumours, 1 myocardial infarction, 1 stroke, 1 road accident and 1 suicide).

As regards living liver donation, the total figure (23) is too small for statistically meaningful survival rates to be calculated. However, the two Swiss centres participate in the European Liver Transplant Registry

(ELTR), which includes results for the whole of Europe (923 living donor liver transplants). In adults, the rate of graft survival following living donation is 74% after 1 year and 65% after 4 years. In contrast to the results for kidney transplants, graft survival rates are about 5% lower in the first year than those observed with cadaveric livers. This is due to the fact that most cadaveric liver transplants are performed with whole organs (an advantage), whereas only part of the living donor liver is transplanted, which creates difficulties particularly during the initial stage prior to regeneration. For this reason, liver function is also initially impaired in 5.5% of liver donors, in addition to other problems (bile leakage 3.4%, biliary strictures 0.8%, pulmonary embolism 0.7%, portal vein thrombosis 0.3%, etc.), with an overall postoperative complication rate of 19%. According to the ELTR, the risk of dying as a result of liver donation is 0.4% (i.e. 10 times higher than with living kidney donation), but a figure of 1% is quoted to potential donors at the Geneva centre – as a deterrent. Psychiatric complications, such as post-donation depression, are also observed following liver donation, but these are not recorded in the ELTR (in contrast to the Swiss kidney donor registry). Plans to include monitoring of the health of living liver donors in the SOL-DHR from 2004 are therefore to be welcomed.

Living donation has become an established part of haemopoietic stem cell (formerly bone marrow) transplantation and kidney transplantation. It also has a key role to play in liver transplants, if one is not prepared to accept the death of about a third of all patients with end-stage liver disease.

3 - Ethics of living donation: beyond coercion and commerce

An outline of the state of the debate

Andrea Arz de Falco

In the international literature, the living donation of organs, tissues and cells has been a subject of intense ethical debate for about two decades.² In the mid-1950s, at the beginning of the transplantation era, living donation was the only practicable method of obtaining organs for transplantation; however, its importance subsequently declined with the rise of brain-death donation.³ Only in the last two decades has it again played a more significant role, largely as a result of the shortage of organs from brain-dead donors and the improved prospects of successful treatment offered by living donor organs (for details cf. Section 2)

Living donor organ transplantation differs from other types of treatment in that the resource utilized to cure a patient is obtained from the body of a second individual. For the latter, this type of intervention always involves a breach of physical integrity. Although the cells, tissues, partial or whole organs removed are not essential to the individual's survival, a number of risks are associated with the operation and its consequences. In some cases, adverse short- or long-term effects are more or less likely to occur.

The traditional Hippocratic approach to medical practice is governed by the overarching principle of the avoidance of harm. The prohibition on causing harm (*primum nihil nocere*)⁴ would rule out *per se* the removal of organs from a living donor. The only possible exception would be a situation in which removal is in the therapeutic interests of the donor. This is the case in so-called domino procedures where, for example, a patient's healthy heart is explanted in order to improve the prospects of a successful lung transplantation (cf. Section 4.3.4). However, a comprehensive ethical view of living donation cannot be obtained by focusing exclusively on the principle of avoidance of harm. In addition

² Arntz Klaus, „Die Organspende zwischen passiver und aktiver Akzeptanz. Ethische Leitlinien zur aktuellen Diskussion“, *Zeitschrift für medizinische Ethik* 49 (2003): 185–201. Baumann Eva, „Organspende unter Lebenden: Über den Vorrang der Missbrauchsverhütung“, *Ethik in der Medizin* 10 (1998): 43–44. Gutmann Thomas/Schroth Ulrich, *Rechtliche und ethische Aspekte der Lebendspende von Organen*, In: Fuat S. Oduncu/Ulrich Schroth/Wilhelm Vossenkuhl (Hg.): Göttingen: Vandenhoeck & Ruprecht 2003, 271–290. Mitchell L. Shiffman et al., Living Donor Liver Transplantation: Summary of a Conference at the National Institutes of Health, *Liver Transplantation* 8 (2002): 174–188. David Price, Legal and Ethical Aspects of Organ Transplantation, Cambridge 2000. Mark W. Russo/Robert S. Brown, Ethical Issues in Living Donor Liver Transplantation, *Current Gastroenterology Reports* (2003) 5: 26–30. Gilbert Thiel, Organlebenspende in der Schweiz – ein Erfahrungsbericht (unpublished manuscript), Basel, 17 March 2003. Fuat S. Oduncu/Ulrich Schroth/Wilhelm Vossenkuhl (Eds), Transplantation. Organgewinnung und -allokation. Göttingen: Vandenhoeck & Ruprecht 2003, Part III. Stella Reiter-Theil, Altruismus mit ethischen Komplikationen? Erfahrungen aus der Begutachtung vor Lebendnierenspende. *Zeitschrift für medizinische Ethik* 45 (1999): 139–148.

Detailed bibliographies are included in the works by Gutmann/Schroth and Price.
³ Walter Land, Verwandte und nichtverwandte Lebendspende-Nierentransplantation. Klinische Ergebnisse. In: Fuat S. Oduncu/Ulrich Schroth/Wilhelm Vossenkuhl (Eds): Transplantation. Organgewinnung und -allokation. Göttingen: Vandenhoeck & Ruprecht 2003, pp. 211–221.

⁴ Ronald Munson, Intervention and Reflection. Basic Issues in Medical Ethics. 4th ed., Belmont, CA: Wadsworth 1992, pp. 32–34.

to the injunction against causing harm, medical ethics encompasses a number of other guiding principles. According to one frequently cited account, medical practice should be based on the following four principles: (1) respect for autonomy, (2) non-maleficence, (3) beneficence and (4) justice.⁵ Two of these four principles are of direct relevance – the principles of autonomy and beneficence. Both of them would be violated if living donation were to be prohibited on the basis of an absolute principle of non-maleficence.

One central ethical requirement is that people should be entitled to take decisions concerning their physical integrity themselves. Respect for autonomy is closely connected with the notion of human dignity. This finds expression in the idea that people should never merely be used as means to an end, but should always be treated and respected as individuals with ends of their own. In a medical context, this relates to specific actions on the part of patients: expressions of consent, requests, wishes, refusals. Autonomy is thus primarily a principle designed to ward off unwanted interventions or paternalistic behaviour. Recognizing individuals as such is essentially equivalent to respecting their right to lead their life according to their own conceptions of the good, as long as they do not harm others as a result. According to the principle of autonomy, people have a moral right, in certain situations, to take decisions that may involve risks in order to achieve a goal they deem to be morally right, and they are entitled to have their wishes heard and respected. It is not possible to assess in purely objective terms the reasonableness of a decision to accept a risk. Ultimately, the crucial factor in such a decision is not the quantifiable medical risk, but the individual's value-judgements and outlook on life. Thus, if someone wishes to donate an organ, tissue or cells to someone else (known or unknown), has the capacity to consent and has been informed about the relevant circumstances and consequences of the decision, this decision is to be respected in accordance with the principle of autonomy.

The second ethical principle that is relevant in this context is that of beneficence. It is beyond question that the act of donation is of benefit to the recipient. Donation is thus an act of direct beneficence. In the debate, this principle is also expressed in the statement that, overall, donation increases the benefits for the parties concerned. Some of these benefits may accrue to the donor. For the donor, the act of helping may have a positive value in itself, developing and strengthening the donor's own personality, favourably influencing the relationship with the recipient, creating new possibilities for their life together, etc. Although these hoped-for consequences cannot be presupposed in every case, they may significantly influence the individual decision from the donor's perspective. While risks to relationships certainly also need to be taken into account, the debate shows that the principle of beneficence is not compatible with a categorical rejection of living donation.

The primacy of autonomy does not however relieve physicians of their responsibilities, and it also allows them to decide autonomously to refuse to perform an intervention that they judge to be unacceptable. Fundamental ethical problems would be raised by the establishment of norms for living donation based on the success of treatment or graft

⁵ T. Beauchamp/J. Childress, *Principles of Biomedical Ethics*, Oxford: OUP, 5th ed., 2001.

survival times. Prescribing a minimum period for a successful outcome would be tantamount to defining a condition that is not worth curing.

3.1 Voluntarism

Among the requirements that need to be met if it is to be permissible to remove an organ from a healthy individual are the donor's informed consent, a strictly voluntary decision and the noble motive of a desire to help, even though self-interested motives may understandably also be a factor in the decision-making process. Gutmann and Schroth state that personal autonomy is characterized by "a certain balance between self-interested and altruistic motives".⁶ In the case of biologically or emotionally related individuals, regulations and the actual practice of living donation must ensure the voluntary nature of the decision to donate, especially through careful handling of any – possibly subtle – psychological pressure exerted on the donor by the recipient or family members. Careful consideration needs to be given not only to the absence of coercion but also to the donor's fundamental decision-making capacity as a prerequisite of informed consent and a stable decision. However, voluntariness is not synonymous with the absence of constraints, freedom from moral obligations and a lack of personal ties. Living donors are *always* forced to make a decision. Or, as some authors have put it: There is no escape from the tension between the opportunity to help and the burden of decision-making. Clearly defined procedures and expert advice may, however, play a significant role in easing such situations.

3.2 Risk of commercialization

In cases where the donor and recipient are unrelated or possibly do not even know each other, there is an ever-present risk of commercialization. Essentially, the debate indicates that there are good reasons why this risk should be averted. However acute the potential recipient's need or the immediate threat to life may be, the fact that the human body and organs are not marketable commodities must not be disregarded. Ultimately, this non-saleability is an expression of human dignity, although arguments have focused less on these matters of principle than on the numerous possibilities for abuse, in the sense of exploiting the plight of the socially disadvantaged. Each individual case of anonymous living organ donation needs to be assessed particularly carefully – especially with regard to the questions of non-commercialism and informed consent (cf. Section 4.3.2). According to Eva Baumann,⁷ it is important that decision-making procedures for potential donors should be designed so as to strike a balance between the prevention of abuses and respect for autonomous decisions.

⁶ Thomas Gutmann/Ulrich Schroth, *op. cit.*

⁷ Eva Baumann, *op. cit.*

4 - Opinion no. 6/2003

On the regulation of living donation in the transplantation law

4.1 Preliminary remarks

The key points of the Commission's recommendations to Parliament were approved at the plenary meeting held on 2/3 July 2003 and were immediately submitted, in the form of a concise version, to the National Council's Committee for Social Security and Health (CSSH-N).⁸ As well as the recommendations, the detailed version of the Opinion, now completed, presents the ethical considerations taken into account by the NEK-CNE. The definitive text of this version was approved on 17 November 2003, following discussions at plenary meetings held on 27 August and on 22/23 October.

The drafting of the Transplantation Law pre-dated the establishment of the NEK-CNE. When the draft Law was reviewed by the Commission, it became apparent that certain ethical issues needed to be clarified in connection with the regulations concerning living donation, i.e. the donation of organs, tissues or cells from living individuals to patients. The recipients are often relatives or close friends of the donors. In the view of the NEK-CNE, the draft Law does not adequately address the complexities of living donation. In particular, it fails to provide adequate protection for donors, who may themselves be prepared to accept major risks in order to cure relatives and friends. Appropriate regulations could, however, also be introduced in an associated Ordinance.

The topic of living donation was initially selected in response to an inquiry from the Federal Office for Social Security (BSV) and the Federal Commission on Fundamental Principles of Health Insurance (EGK) concerning the inclusion of living liver donation on social health insurers' official list of reimbursable items. A separate Opinion (no. 5/2003) on the financing of living liver donation was issued by the NEK-CNE in October 2003, *supporting* reimbursability.⁹ The topic of living donation was also regarded as particularly urgent for various objective reasons. Accordingly, it was necessary to defer consideration of other problematic areas of transplantation medicine that are doubtless of equal ethical significance – e.g. xenotransplantation, organ allocation procedures, or determination of the time at which death occurs. These ethical issues have already been comparatively widely discussed.

⁸ This concise version is available on the Commission's website in French, German and Italian: www.nek-cne.ch

⁹ See Appendix (also available on the Commission's website in French, German and Italian: www.nek-cne.ch)

4.2 Problems specific to living donation: ethical issues

The growing importance¹⁰ of living donation in transplantation medicine is a welcome development, given that patients may die on the waiting list as a result of the shortage of cadaveric organs. From the donor's perspective, the possibility of donating organs, tissues or cells to fellow humans in need may represent a practical expression of charitable instincts. The donation of an organ may be a life-saving gift and thus also an important concern for the donor.

At the same time, this option gives rise to new kinds of medical, social, legal and also ethical problems, which require careful management. In particular, donors may face health-related and psychosocial risks that are difficult to weigh up. In relationships characterized by caring or dependency, the responsibility may also be overwhelming.¹¹ People who care for others may become vulnerable as a result of exhausting their own resources. In addition, a fundamental conflict arises: as the preferred medical option, the grafting of organs from living donors could broaden the indication for transplantation. A society that establishes a transplantation system has a duty to protect the fundamental right of individuals not to have their bodies used for the benefit of others. The transplantation of organs, tissues or cells from living donors may, however, be acceptable if it is ensured that decisions are made voluntarily by the parties concerned. But as the following analysis seeks to show, this is a relatively complex task.¹²

A variety of ethical questions arise. These relate to the entitlement of those concerned to weigh competing goods autonomously, according to the circumstances of the individual case; the diversity of dependency relations within the families of donors and recipients; the entitlement of autonomous prospective donors to have their wishes respected; and finally the extent and nature of the state's obligation to protect the individual. We first examine (4.2.1) the fact that living donation may involve risks and imponderables for donors, (4.2.2) the relationships between donors and recipients, and (4.2.3) the issue of voluntariness. We then consider (4.2.4) the special questions arising in cases where living donor organ transplants are performed in acute emergencies and (4.2.5) the evident need to justify living donation given that the removal of an organ, tissue, or cells from a healthy individual conflicts with one of the fundamental principles of medical ethics – that of non-maleficence. Finally, we also outline (4.2.6) the ethical problems from the perspective of the donor as a subject with an individual moral responsibility. On the basis of these considerations, the Commission's recommendations to Parliament are presented in the

¹⁰ In 2002, the number of organs recovered from living donors exceeded the number obtained from brain-dead donors for the first time in Switzerland – cf. Martinoli Sebastiano, *Swisstransplant 2002: rapport d'activité avec quelques remarques ...*, *Bulletin des médecins suisses* 2003, 84 (36): 1827–1828.

¹¹ For an ethical discussion of "dependency relations" see Eva Feder Kittay: *Love's Labor*. New York: Routledge 1999.

¹² In addition to the relevant literature, this analysis is based on the expert report submitted to the NEK-CNE by Dr Ruth Baumann-Hölzle (Zurich, July 2003): "Ethische Überlegungen zu Lebendspende von menschlichen Organen, Geweben und Zellen im Rahmen des Legiferierungsprozesses des CH-Transplantationsgesetzes" (available on the website in German only).

following Sections 4.3 to 4.8. Specific recommendations are highlighted in **bold**.

4.2.1 Risks for donors

Organs, tissues and cells differ – sometimes substantially – with regard to the *risk* that their removal poses for the donor. However, since living donation always represents a serious intervention, careful decision-making is essential in each individual case. In this connection, the draft Law (Art. 12 c) requires only that there should be “no serious risk to the donor’s life or health”. However, when organs or organ parts are removed from living (particularly liver) donors, serious complications may occur, including even death in isolated cases, and certain donors would themselves accept high levels of risk. There is therefore a special need to protect such individuals. But since recipients as well as donors may be subjected to pressure to consent to transplantation, appropriate legal safeguards are also required in this area.

As different organs are associated with different levels of risk, one might consider assigning organs to various categories according to the degree of risk involved. A higher level of care, supervision and support for the decision-making parties could then be stipulated for certain categories, while simplified procedures would be applicable for others. On closer examination, however, it would appear to be very difficult to generalize assessments of risk. In view of differences in donors’ state of health, the risks may vary substantially for the same organ and will also depend on surgeons’ technical skills and experience. In addition, the essential evaluation of the risks cannot be expressed in statistical terms, but involves subjective aspects such as values, life plans, sensibilities, hopes. The perceived level of risk also depends on the attitude of the parties concerned to living donation. A further argument against an organ-based classification of risks is provided by a comparison of the liver and kidney: although the risks associated with living liver donation are statistically much greater than with living kidney donation, it should also be borne in mind that the liver is an organ capable of regeneration, whereas kidney donation involves the irreversible elimination of an organ (even though a second kidney is present). Differences in the risk level may be counterbalanced by these additional factors. A careful assessment, sensitive to differences in individual risks, is therefore to be preferred for *all* proposed living donor transplantation procedures.

Decision-making procedures should therefore be designed to permit flexibility, so that the controls imposed are neither too strict nor too lax. *Excessive*, centralized controls should not be imposed against the will of those concerned, e.g. in the case of less severe interventions (such as the donation of bone marrow cells). Equally, however, the precautionary measures stipulated should not be *less stringent* than is required to ensure high-quality decision-making in the unpredictable circumstances of the individual case. Procedures designed to support decision-making should be independent, transparent, based on a sufficiently broad range of expertise, and of a binding nature. Adequate provision should be made for procedures of this kind, and of

the requisite quality, in individual situations perceived as difficult. From our point of view, this type of support, sensitive to the requirements of the individual case, is preferable to a graduated control system based on predefined categories. An elaborate system permitting in-depth and comprehensive individual risk assessment must be an integral part of professional practice.

4.2.2 The relationship between donors and recipients

The traditional view has been that there is a particular need for additional investigations in cases where organs are donated by unrelated individuals. In various countries (e.g. Germany and the UK), transplantation legislation places restrictions on unrelated donation. In Switzerland, the draft Transplantation Law includes no such restrictions; instead, the decision is left to the donors concerned. ***The NEK-CNE supports this position.*** This necessitates careful investigations in individual cases so as to exclude covert exchanges or commercial dealings.

With regard to the commercialization of organs, there have recently been calls from several quarters for a more liberal approach, in view of the existing organ shortage; this could take the form, for example, of a regulated market for kidneys obtained from living donors. The arguments put forward include the avoidance of grey areas and black markets, improved medical aftercare for donors involved in legal transactions, and the promotion of fair trade with appropriate pricing.¹³

However, studies show that the situation of people who sell one of their own organs for economic reasons is frequently not improved. Often they soon find themselves economically in the same position as before the operation. Moreover, in some cases, their health deteriorates as a result of inadequate medical aftercare,¹⁴ which also adversely affects their economic situation. Trade in human organs tends to lead to exploitation of socially deprived groups in economically weak countries. ***For this reason, the provisions in the Law prohibiting the commercialization of organs are to be welcomed.*** Medical ethics has always been opposed to exploiting the plight of the socially disadvantaged.

On the other hand, agreements involving the granting of privileges to donors could be discussed in less categorical terms: The privileging of individuals who are themselves prepared to donate an organ is rejected in the draft Law. One argument in support of this position is the fact that discrimination is prohibited. In addition, it is not certain whether the introduction of a system of incentives – for which some substantial arguments have been advanced¹⁵ – would actually lead to a significant increase in the supply of organs.

¹³ Cf. Michael Friedländer, The right to sell or buy a kidney. Are we failing our patients?, *Lancet* 2002, 359; 971–973

¹⁴ Madhav Goyal et al., Economic and health consequences of selling a kidney in India, *Journal of the American Medical Association* 2002, 288 (13); 1589–1593

¹⁵ It has been argued, for example, that the state has a legal duty to care for its citizens, and that it would be neglecting this duty by failing to introduce a system of incentives, if such a system would in fact help to increase the supply of organs.

However, as a matter of justice and an expression of society's solidarity, it is essential that donors should not suffer any additional disadvantages with regard to insurance and that they should be compensated for any possible late effects. It is proposed that these costs should be borne by recipients' insurers.

Living donation raises the question of whether former donors should be granted a privileged status if they themselves subsequently require such treatment.

There is a connection between living donation and the introduction of arrangements designed to increase people's willingness to donate organs in the event of brain death, since a shortage of organs from brain-dead donors leads to an increased demand for organs from living donors. Various models exist. In contrast to the so-called club system, where membership has to be actively sought, another conceivable model would involve an annually renewable declaration – on a tax return, health insurance policy, or driving licence – of willingness to donate organs in the event of brain death. However, a new question then arises: if an individual develops a disease that is likely to necessitate transplantation, does the existing decision remain valid? In addition, for health reasons, some people are not eligible to become donors; would they nevertheless be entitled to receive a transplant should the need arise? Overall, however, a system that would help to increase donation rates could ease the demand for living donor organs.

It is evident that gender-related aspects also play a significant role in the relationship between donors and recipients. For example, data indicate that the ratio of female to male donors is approximately 2:1.¹⁶

4.2.3 Voluntariness of living donation

The Law should ensure that the principle of voluntariness is respected, both for donors and for recipients, and guarantee the provision of aftercare. In the case of close family relationships, one cannot simply conclude on the basis of the donor's declared wishes that the risk is being accepted voluntarily. The procedures designed to support and review decision-making should ensure voluntariness and at the same time should enable donors and recipients to conduct a comprehensive assessment of the risks in relation to their specific situation.

Free will is to be understood as self-determination and the exercise of responsibility. In the case of organ donation, voluntariness is an essential requirement for the various parties concerned, and specifically in three respects:

- donors make an organ available of their own free will,
- recipients accept a donor organ voluntarily,

¹⁶ Land, Walter: "Verwandte und nichtverwandte Lebendspende-Nierentransplantation. Klinische Ergebnisse." In: Fuat S. Oduncu/Ulrich Schroth/Wilhelm Vossenkuhl (Eds): Transplantation. Organgewinnung und -allokation. Göttingen: Vandenhoeck & Ruprecht 2003, pp. 211–221
Documentation submitted to the NEK-CNE by Prof. G. Mentha, University Hospital of Geneva (HUG)

- the medical staff perform the transplantation procedure voluntarily.

All of the parties concerned thus take responsibility for their own action and for the consequences thereof. In general, the most difficult decision rests with the donors, who consciously and often spontaneously accept various risks that may produce lasting changes in their lives. In addition to the health risks, which vary in severity according to the type of donation, there is a risk that established relationships may be altered or even terminated.

It is therefore of crucial importance that decisions on organ donation should be taken autonomously and on the basis of a stable personality. Existing relationships and dependencies are also inherently relevant to the individual's decision. An autonomous decision does not proceed from the idealized notion of a wholly independent person, but takes account of the individual's biography and social relations.

This gives rise to a number of specific problems and tasks. Bearing in mind the conception of an autonomous and voluntary decision, the question of authenticity needs to be considered, i.e. whether the decision reflects the donor's true self. Prospective donors should be able to examine whether their decision is soundly based, what the underlying motives are, and how these motives are to be regarded.

The question of whether a decision is authentic can also be raised within close relationships, where pressure to donate inevitably arises. Additional points to be considered are the donor's mental competence, capacity for self-reflection and ability to decide freely what course of action to adopt. In this connection, attention needs to be paid to existing problems in relationships, conflicts and dependencies. Another question to be carefully examined is whether transplantation could have adverse consequences for donors and recipients. These will depend on the personality of the individuals concerned, the nature of their personal relationship and the type of transplantation performed. In considering the question of underlying motives, it is often easier to make an assessment with the assistance of an experienced, psychologically trained professional.

4.2.4 Emergencies

With regard to living liver donation, a special situation arises in the case of acute liver failure. Depending on the etiology, the survival rate with traditional therapy or substitution of liver function (bioartificial systems) is around 20%. Following transplantation, the survival rate rises to about 70%. In view of the exceptional regenerative capacity of the liver, the risks of intervention need to be carefully weighed against those of non-intervention. It should also be borne in mind that the conditions for transplantation are not ideal, given the acute nature and fulminant course of the recipient's disease.

The ethical problems arising in connection with emergency living donation are essentially the same as for living donation in general, although the problems are aggravated by time pressure. Particularly important from an ethical viewpoint is the fact that the time required

for a decision-making process is not available. Such a process should be as free of constraints as possible and should include time for reflection, with the possibility of reconsidering one's decision. In addition, the dramatic nature of the situation – the immediate threat to the recipient's life – will arouse such intense emotions that it will be difficult or even impossible to make an autonomous decision (which would require a degree of critical detachment). In such circumstances, however, it is ethically questionable to deny a potential donor – purely in the interests of preserving autonomy – the right to donate an organ to a loved one. Indeed, it would be contradictory to restrict the freedom of an individual who wishes to consent to donation on the grounds that decision-making autonomy must be protected. But if a decision taken under such precarious circumstances is to be considered acceptable, ***it is essential that the transplantation of a liver from a living donor should be medically judged to be the only viable treatment option, with no possibility of achieving a successful outcome by using alternative methods – traditional therapies or substitution systems.***

The ethical tension between the need to protect healthy individuals from harm and at the same time to respect their autonomy cannot be resolved in a general manner for the case of emergency living donation; instead, a careful examination of the particular case is called for. Procedures should be established which, even in this precarious situation, provide some guarantee of protection for the donor and safeguard autonomous decision-making. The fact that the voluntary nature of the decision is not assured in this *emergency aid* situation does not represent an ethically sound argument against the moral rightness of the decision.

Another aspect to be considered is the type of relationship between the donor and recipient. As is generally the case for living donation, the issue of genuine voluntariness or authenticity needs to be addressed when the donor and recipient are biologically related or have a close emotional relationship. This should be confirmed if possible by another person close to the parties concerned. In a dramatic situation of this kind, the risk of commercial dealings is relatively low. ***However, in cases where living donation is performed in an emergency – given the risks and the problematic decision-making situation – a very close relationship must exist between the donor and the recipient if the procedure is to be ethically acceptable.***

4.2.5 Medical ethics and the principle of non-maleficence

The principle of non-maleficence (*primum nihil nocere*, "first, do no harm"), one of the cornerstones of medical ethics, dates back to the Hippocratic Oath. Essentially, this principle is violated whenever an organ is removed from a living donor, as the procedure constitutes a deliberate physical injury. Accordingly, in an ethical assessment, the benefits of living donation must by far outweigh the potential harm to the donor. In making this calculation, the benefits and risks for donor and recipient should not be combined; instead, the benefits should outweigh the harm for each of the two parties considered individually. The benefits for the recipient are readily apparent: the health of a

seriously ill individual, who would otherwise have remained ill or even have died, is largely restored. The assessment is far more difficult in the case of the donor: since the donor's state of health after organ donation is at best as good as before the procedure, benefits must be evident at the psychological or social level. The benefits can be readily appreciated and assessed in cases where the risks of surgery are low and a strong emotional attachment exists between donor and recipient. If a mother or father donates an organ to a critically ill child, any physical damage suffered as a result of the operation will be offset by the psychosocial "gains" associated with improving a child's quality of life or even saving its life. The risk-benefit ratio needs to be assessed particularly carefully in cases where the psychosocial benefits for the donor are less evident.

For physicians involved in living donation and transplantation procedures, the non-maleficence principle thus creates a special responsibility: before any decision, an ethical assessment must be undertaken, considering all the relevant medical and psychosocial factors. A breach of the non-maleficence principle in the short term must be offset by favourable long-term results for all concerned. However, it should also be borne in mind by all parties that a certain risk of miscalculation remains inevitable (even after careful assessment).

4.2.6 Greater scope for solidarity: opportunity or responsibility?

Although the individual ethical problems raised by donation are not the subject of this Opinion, it is important to consider them in order to understand the questions to which the Law needs to provide answers that are ethically acceptable in individual cases. Individuals considering the possibility of donation cannot be ethically obliged to consent to the procedure. However, they may well feel that donation represents a personal task and responsibility, as an expression of solidarity. The State has a duty to establish an acceptable framework within which the individuals concerned can express their solidarity.

The possibility of providing relatives, partners or even people we do not know with organs, tissues and cells as a living donor opens up a new area of interpersonal responsibility. In certain situations we can now come to the aid of our fellow humans by donating parts of our own body. This is the new element – the gift is not part of our property, something we produce or a service we perform, but part of ourselves. Parts of the organism can be used as transplants if they are not required for our own survival. If the opportunity to help in this way presents itself, the ethical question arises whether this does not place excessive demands on the individual's solidarity. From the perspective of potential donors, two questions arise: whether there is a moral responsibility to shoulder other people's burden by donating parts of their own body, and if so how far this responsibility extends. Conversely, it may also be asked: if a situation arises in which someone to whom we are attached is in a critical condition and could be saved by the donation of part of our body, do we – as a potential donor – have a moral right to refuse? Does the option even exist of

saying no and still maintaining a healthy relationship?¹⁷ From the partner's viewpoint, when could this option ever be morally sound?

The question of responsibility (and the limits thereto) arises in various forms, according to whether donation involves (1) constantly renewed cells (such as blood or bone marrow) or regenerative tissue (e.g. parts of the liver) or (2) non-renewable body parts. There are special cases where either (2a) an organ – such as the kidney – is duplicated in the body and is biologically redundant or (2b) the removal of an organ or part of an organ (e.g. a portion of the intestine) produces functional restrictions that appear to be acceptable. However, in cases where (3) vital parts of the body are involved, there can be no obligation for living subjects to donate, although, subjectively, potential donors may take a different view.¹⁸

At the same time, it is also important for recipients to be aware that donation was undertaken voluntarily and not simply because the donor felt pressurized. Otherwise, the transplantation would subsequently become a moral burden.¹⁹

From the perspective of donors and recipients, the question of symbolic significance also arises: is a donation undertaken from a sense of gratitude, or guilt? It is not clear a priori whether organ donation may not form part of an exchange. Should it be a gift that helps to maintain a relationship, or must it represent a selfless token of love, not associated with expectations of any kind?

At all events, the development of transplantation medicine in the area of living donation and the ever-widening range of organs, tissues and cells that can be transplanted from living donors represent a significant expansion and transformation of interpersonal solidarity. A historically unprecedented way of feeling and exercising moral responsibility has arisen, a new opportunity to help fellow humans in need – by donating part of one's own body. The development of living donation is thus also a culturally significant innovation. It should not merely be regarded as a means of relieving the shortage of donor organs or of shortening waiting lists.

¹⁷ Following a living liver donation to his wife, a husband said: "What else could I do? I could not just lose her." (Gift from a loving husband: Part of himself. *The New York Times*, August 2, 2003.)

¹⁸ A legal dispute arose when a man named Prendergast, father of two sons, initially donated one of his kidneys to the first son, who was suffering from renal insufficiency and dependent on dialysis, and later, when the second son also suffered renal insufficiency, wished to donate his second kidney. However, no surgeon could be found who was prepared to perform the operation. The case was resolved when the mother donated an organ for the second son. (David Price: *Legal and Ethical Aspects of Organ Transplantation*. Cambridge: Cambridge University Press 2000, p. 249.)

¹⁹ As a recipient said of her husband, who had donated a liver lobe: "I know enough to know I don't want to live with a man who's going to have regrets afterwards. But it was his idea. He wanted to do it." (Gift from a loving husband: Part of himself. *The New York Times*, August 2, 2003.)

4.3 Special donor/recipient constellations

4.3.1 Related donors and recipients

Especially in cases where the donor and recipient are members of the same family, there may be a high level of pressure, but also willingness on the part of the donor to accept risks to one's health. A legally defined procedure is therefore required to help protect potential donors from acting without due consideration and making a decision that they cannot subsequently justify to themselves.

As outsiders, it is difficult for members of a transplantation team to gain an insight into the structure of a relationship, with all the various dependencies, within a short time. What is required in particular is the ability to distinguish a genuine, autonomous desire to donate an organ from wishes that are expressed from a sense of dependency or guilt and as a result of moral pressure. With certain types of relationship – e.g. donation from parent to child or between spouses – it may be easier to analyse the situation. But in other cases – e.g. when a child is to donate to a parent or sibling – hidden dependencies and moral pressure may well cast doubt on the voluntariness of the decision.

A person who is considering donating an organ to a relative should therefore undergo assessment in accordance with a set procedure, permitting a review of the individual's motivation (autonomous desire, dependencies, conflicts of conscience and inescapable pressure). A care team should be available for this purpose. The procedure should provide a framework for free and independent discussion of the entire situation. This information and assessment process should include the viewpoint of an independent third party, i.e. someone not connected with the transplantation team or the family.

The NEK-CNE proposes that the provisions of Article 12 should be clarified and elaborated, although the provisions could also be included in Article 14 Paragraph 2 (or in the Ordinance in which the requirements for informed consent are specified by the Federal Council):

Prior to organ donation, the care team must provide donors with comprehensive information on medical and psychosocial aspects. In addition, donors must be entitled to receive comprehensive medical, nursing and psychosocial care before, during and after organ removal. Lifelong aftercare is to be provided.

The care provided for donors must not be discontinued once the organ has been removed. They are entitled to receive medical/nursing aftercare, since health problems associated with organ removal may occur long after the original procedure. Psychosocial care should also be available over the long term if required. This is an area where problems may well arise for donors – coming to terms with what has happened – long after the operation. Living donation can alter relationships, reawaken or create new conflicts, or even lead to a break-up, which is difficult for those concerned to cope with. In such

situations, the people involved should have access to external care, if necessary for the rest of their life.

4.3.2 Anonymous donation

Living donation is essentially a difficult situation for physicians. In view of the non-maleficence principle, compelling reasons will be required if they are to remove an organ from a healthy subject. In the case of anonymous donation, the motive of providing an organ for a person with whom the donor has a close relationship is lacking. The donation is intended to benefit an unknown person ("non-directed"). The NEK-CNE does not wish to assess the motives and reasons that lead certain individuals to undertake anonymous living donation. It notes that such requests are rare and considers it to be possible in principle to permit anonymous donation. However, special regulations should be established for such cases:

- 1. Anonymous donors should undergo the same procedures as donors who have close relationships with the recipients.***
- 2. Organs from anonymous donors should be allocated according to the same criteria as organs from brain-dead donors. This will enable patients without close relatives to benefit from living donation.***

With regard to the first point: Exceptionally, a healthy individual may decide to donate an organ to an unspecified recipient. Although in this type of case there are no donor/recipient relations to be taken into account, it is nonetheless essential to undertake a comprehensive assessment of the prospective donor. In particular, the reasons underlying the desire to donate are to be carefully assessed. Special attention should be paid to the question of whether these reasons are sufficient to justify a breach of the principle of non-maleficence. It is therefore recommended that the same care should be exercised in the assessment procedure for anonymous donation as for cases where the donor and recipient have a close relationship.

With regard to the second point: Since there are no restrictions as to the recipient in the case of anonymous donation, it would appear equitable to apply the same allocation criteria as for organs from deceased donors. This entails that an anonymous donor should not be entitled to impose any restrictions on the selection of a recipient.

This may appear to run counter to the individual's right to determine what is done with one's own body as one sees fit. However, the requirement that organs should be justly allocated according to the criteria of need and the prospects of a favourable medical outcome – rather than the wishes that happen to be expressed by an anonymous donor – is an argument in favour of restricting the donor's discretion and against establishing a special pool or special arrangements for anonymously donated organs. A second argument is that the very possibility of imposing restrictions as to the choice of recipient could lead to certain people feeling pressurized to become anonymous donors so as to donate organs to specific, particularly needy groups.

4.3.3 Crossover transplantation

If it is not possible for immunological reasons to donate an organ to a relative (e.g. a spouse or other family member), organs may be donated in an exchange between two couples that are incompatible within themselves. In what is known as “crossover transplantation”, various combinations of couples are sought in order to make compatible living donation possible where this would not otherwise be so. Brain-dead donors may possibly also be combined with living donors.

This raises a number of specific ethical questions:²⁰

- a) Is the psychological “gain” for donors reduced? In these constellations, the gift is made not to a relative, to whom the donor has an emotional attachment, but to a selected stranger. The link to the closely related individual is indirect. However, only the prospective donors can assess whether and how far their motivation to donate is affected by this fact. It would not be advisable to impose a general restriction on crossover transplantation for this reason.
- b) Will transplantation practice be broadened as a result? As graft survival is better after living donation than after brain-dead donation, a therapeutic interest exists in seeking out and bringing together groups of couples for crossover transplantation. However, this cannot represent an objection of principle to crossover transplantation. Rather this point needs to be taken into account in the assessment carried out in the individual case.
- c) Does the fact that the recipients do not know the donors create a psychological “cost factor”? Once again, this factor is highly individual and can only be perceived by the parties concerned. In general, the cost factor does not argue against this type of arrangement.
- d) Does crossover transplantation intrinsically involve a kind of commercial relationship? Although the donor him/herself does not expect any reward from the recipient, the donation is only made to make it possible for the donor’s relative to receive an organ from a third party. The gift of a compatible organ is both a condition of the donation and a quid pro quo. However, the transaction cannot be classified as commercial because the quid pro quo does *not* consist of an advantage that differs from the benefit provided by the donation itself, as would be the case, for example, with a payment. The exchange relates to the donated organ itself. As a result of the crossover arrangement, it is merely “converted” into an immunologically compatible organ. The possibility of individuals being exposed to pressure is no different from the situation with direct donation. This means that the same support programmes should be required for crossover transplantation, not that legal restrictions should be imposed on this type of procedure.
- e) Is the risk of commercialization increased with crossover transplantation? A crossover arrangement could be purchased by the recipient – this would be prohibited by the Transplantation Law.

²⁰ Cf. Conseil d’Ethique Clinique des Hôpitaux Universitaires de Genève: Don d’organe entre vifs (2003), Chapter 4; L. Ross, Ethical Issues in Innovative Transplant Protocols. *Forum: Trends in Experimental and Clinical Medicine* 7 (1997): 256–272.

However, such transactions can only be detected in specific cases, and the risk attaches essentially to all types of donor/recipient constellation. The planned prohibition on trade in organs provides a sufficient basis for prevention.

- f) Does the recipient have a right to become acquainted with the donor? Experience has shown that it is usually difficult to ensure that the couples' anonymity is maintained, as in typical crossover arrangements four patients have to be cared for and treated by four teams at a single institution. However, while this fact does not argue against crossover transplantation, it should be disclosed to the donors and recipients before the final decision is taken. There can, however, be no explicit "right" to become acquainted with the donor, since organ donation must not be associated with any obligations or conditions imposed by the recipient.

The NEK-CNE therefore sees no reason to introduce special restrictions on crossover transplantation in the Law. The particular difficulties and opportunities that arise can be taken into account in decision-making by the parties concerned. Psychosocial support should be geared to the special circumstances of crossover transplantation. It should also be noted that, compared with standard donor/recipient constellations, crossover transplantation is particularly dependent on organization at the national level to ensure the efficiency and thus the ethical acceptability of this type of procedure.

4.3.4 Domino transplantation

In domino procedures, patients – for reasons relating to the treatment of their own condition – have to undergo the removal of organs, tissues or cells suitable for transplantation, and healthy organs, tissues or cells become redundant as a result. Organ recipients may thus at the same time become donors. This type of situation may arise, for example, when a patient's heart and lung are removed en bloc and a redundant healthy heart thus becomes available as a donor organ.

Nonetheless, the donor's informed consent is also required in these circumstances. Guidance needs to be included in the Law, specifying the conditions that are required for a procedure to be recognized as a domino transplantation and deemed permissible.

- 1. No parts of the body are to be removed that would not have been removed in any case for therapeutic reasons.***
- 2. The donor must not be exposed to any additional risks as a result of the domino arrangement.***
- 3. In addition, the donor's voluntary informed consent is required. It must be ensured that receipt of an organ is not made conditional upon the patient's agreement to donate the redundant organ.***

Justification for points 1 and 2: A domino arrangement implies that there is a medical indication for the removal of an organ, tissue or cell material that is still functional, i.e. the risks for the patient are to be reduced. If the patient is to be exposed to higher risks, or if additional

parts are removed, this is no longer a domino procedure, but comes under the heading of standard donation, where higher risks may possibly be consciously accepted.

Justification for point 3: An organ surgically removed from a patient remains “his/her” property, and the patient thus retains the right to determine its fate. This is not affected by the fact that the organ is still capable of functioning. In this type of situation, donation should therefore also proceed on the basis of the patient’s voluntary decision. Making transplantation conditional on the patient’s consent to donate the usable organ would render a voluntary decision impossible.

4.4 Restrictions on living donation

The NEK-CNE recommends that living donation should be restricted in accordance with the following principle:

Persons should only be permitted to receive an organ if they meet the conditions for admission to waiting lists for cadaveric organs or could meet these conditions in the foreseeable future.

If the restrictions are thus worded, it would also be permissible for individuals not currently on the waiting list to receive an organ. The restrictions would, however, prevent living donor organs from being transplanted in order to cure treatable conditions.

The restrictions proposed by the NEK-CNE relate, not to every living donation of tissue or cells, but to organ donation. In the case of organs, there are essentially two extreme options for the approval of living donation. On the one hand, the law could be non-restrictive, making the donor’s voluntary informed consent the only requirement. This would be the most “liberal” option, and would lead to organs being transplanted even in situations in which an organ from a brain-dead donor would not be released. It would be sufficient if transplantation were desirable for the recipient and medically advisable and if a willing donor were available. On the other hand – the most restrictive option – the law could stipulate that living organ donation should only be permissible if the recipient currently meets the criteria for the waiting list for cadaveric organs. This would exclude an organ being transplanted to a patient at a time when final loss of function is foreseeable but has not yet occurred, even though the prospects of recovery (e.g. in kidney and liver disorders) would be improved if transplantation were carried out before the patient’s condition deteriorated to the point of complete loss of function.

The proposed rule represents a middle way. While permitting the latter procedure, it would make it a requirement that death or severe suffering was otherwise to be expected, so that the waiting list criteria could be met. However, transplantation would be ruled out if it would only produce a slight improvement in the potential recipient’s quality of life or if alternative treatments were available for the patient’s condition.

4.5 National authority for living donation

The NEK-CNE proposes that the following provisions be added to Art. 14: ***The Federal Council is to establish a national authority for living donation, serving an ombuds and advisory function for***

donors and other parties involved and responsible for the evaluation of decision-making procedures.

Ombuds and advisory function:

The assessment procedure and decision-making on living donation are conducted at the appropriate regional centre. However, in view of the wide variety of risks and issues involved, it is important that a higher-level (national) authority should be established where the parties concerned may seek advice – also in the sense of a second opinion. The focus may be not only on medical and psychosocial but also on insurance-related aspects.

Evaluation of decision-making procedures:

In addition to its advisory and ombuds function, the national authority should play a harmonizing role. Without intervening in the detailed aspects of local processes, it should ensure that the key decision-making procedures are similar and of a high standard at all regional centres. In addition, as a quality assurance measure, it should evaluate the latest national and international findings in the field of living donation and communicate these to the regional centres.

4.6 Registry and monitoring

To ensure that the risks for donors are reliably assessed over the long term, the Law should introduce an obligation to maintain a registry of living donors and require regular evaluations.

The findings obtained will also serve as a data base for the national authority for living donation (cf. 4.5). Data protection and voluntariness must be guaranteed. The detailed arrangements should be specified in the Ordinance.

A risk assessment can only be carried out on the basis of comprehensively evaluated, up-to-date information on the long-term health and wellbeing of donors.

4.7 Donation from an embryo or fetus following termination of pregnancy

The NEK-CNE considers the requirement (specified in Art. 38) that decisions on termination of pregnancy be taken independently of decisions on the donation of embryonic or fetal organs, tissues or cells to be indispensable. ***However, the Commission recommends that, in addition to the questions of timing and method, explicit reference should be made, in Art. 36 Para. 1 (or Art. 38), to the fact that the decision on termination of pregnancy must be taken independently of any subsequent transplantation.***

Nonetheless, a dilemma remains, since in practice the decision on termination of pregnancy and the woman's decision on donation cannot be completely separated. However, as mentioned above, the woman's decision should be determined by factors other than the possibility of donation. For ethical reasons, donation can never justify a

termination of pregnancy. A physician should therefore never enquire about donation prior to a termination.

4.8. Relationship to the Council of Europe's Oviedo Convention (Convention on Human Rights and Biomedicine) with regard to donation by individuals lacking legal capacity/mental competence

Under Art. 13 of the draft Transplantation Law, the removal of organs, tissues or cells from an individual lacking legal capacity or mental competence is essentially prohibited – with one exception: tissues and regenerative cells (but not organs) may be donated for the benefit of the donor's siblings, parents or children. This exception allows for solidarity within the family. In contrast to this proposal, the Oviedo Convention provides only for the possibility of donation between siblings, and not donation for the benefit of the parents or children of individuals lacking legal capacity/mental competence. In the consultation procedure for the Transplantation Law, it emerged that the restriction imposed by the Oviedo Convention was felt to be too strict.²¹ If the European Convention on Human Rights and Biomedicine were to be ratified by Switzerland, a reservation would be made in respect of the provision (Art. 20) with which the Transplantation Law is not in conformity.

In the case of donation by individuals lacking legal capacity or mental competence, the NEK-CNE does not consider it to be problematic if the range of possible recipients is extended to include the immediate family (siblings, parents and children) and supports the proposal made by the Federal Council in the draft Law.

A minority would, however, also support the possibility of organs being donated by mentally competent individuals who lack legal capacity to consent. Another minority is opposed to the removal of cells or regenerative tissue from individuals lacking mental competence and legal capacity. However, the majority agrees with the Federal Council's proposal.

5 – Background: Personal views of donors and recipients

²¹ Submission concerning the Federal Law on the Transplantation of Organs, Tissues and Cells, dated 12 September 2001 (BBI 2002 29, Section 2.4.3.2)

By conducting interviews with patients and other parties concerned, the Swiss National Advisory Commission on Biomedical Ethics sought to ensure that these individuals' perspectives were also taken directly into consideration. The excerpts from these interviews reproduced in Sections 5 and 6 are designed to illustrate "real life". Although these examples make no claim to be representative, they should provide an insight into the challenges, emotional intensity and human complexities involved in living donation.

5.1 Mr M., recipient

Mr M., the recipient of a kidney donated by his wife, was interviewed by Ruth Baumann-Hölzle.

I'm delighted that you've agreed to be interviewed. You're the recipient of a living donor organ, donated by your wife, and I'm just curious to know how things were before you received the organ. Also, who was it that suggested the possibility of your wife making a living donation. I know you had major problems at that time. What decisions were then taken, and how did this affect your wife? Unfortunately, she's away on holiday just now. Your transplantation took place in April this year?

Mr M.: Yes, on 16th April. We were admitted on the 15th. That was a Tuesday, and on the Wednesday morning kidney out, kidney in.

First I'd be interested to hear about your history. What disease did you suffer from?

For me, it started like this: when I sat for a while, in a restaurant for instance, I noticed that my legs were swollen. I thought nothing of it. But then I did go to the doctor's after all and found out I had too much protein in the blood. From then on, I went to see the doctor regularly. He gave me pills, water pills. My blood pressure was also at the upper limit. And that way I was able to keep things more or less stable for a good 15 to 20 years, also with the right diet, low-salt and low-protein. So things were stable for quite a long time. I didn't notice anything, then all of a sudden the doctor said the creatinine levels were getting higher and higher. That's the crucial thing, really. And then in August 2000 I was at the doctor's again and my blood pressure was very high, 200. I just couldn't get it down again. So the doctor said, now I'll have to arrange for you to see Mr S. That's the specialist at the dialysis centre. But then I was away on holiday for a few days in Valais. When we were about to set off, I had to go to the toilet. Then I suddenly felt ill and I fainted. After that I felt better again, so we did go off to Valais after all. On the first day, we went up a three-thousander and it was fine. But I did realize that something was wrong. Then we came home via the Ticino, and no sooner were we back than the telephone rang. It was Mr S. calling to say I'd have to come and see him first thing on Monday, the creatinine was over 1000. So I went to see him on the Monday and he told me I should have an emergency shunt operation done immediately in Winterthur. They told me there that with that much creatinine you're normally unconscious. And the blood pressure was 240 over 180. It's crazy, when I think about it now. I was really playing with fire.

You just didn't know.

I was resisting it. I wanted to put it off for as long as possible. There was so much I wanted to do. I knew what was going to happen. The doctor told me I'd need dialysis sometime. I always thought it'll be another 3 or 4 years, and then suddenly it was only a year. I had my first dialysis at the end of September 2000. Then it took about 2 or 3 months for my blood pressure to go down. It was alarmingly high. Then that stabilized again. I felt, I'm slowly improving again now. And then the question came up, did I want to be put on the waiting list for a transplant? But I wasn't ready yet. So my wife wasn't involved at that stage. And then after a year I agreed. The doctor advised me to. It's not good to wait such a long time. You never know how long you'll be on the waiting list. Then I had all the checks done that you need to be put on the list – heart, lungs and everything.

The initial decision was to put your name on the waiting list for an organ from a brain-dead donor?

Dr S. said, with my blood group I could expect it to take almost 5 years. And when my wife heard that she said, well, I could give you a kidney. I didn't want her to.

So she was the one who made the suggestion?

Yes, she offered to. I never said anything. I didn't want her to. I said, no, no, I don't want you to.

How did she know that you can make a living donation?

I think Dr S. had told her that some time. When I was having the tests done. She immediately said yes. So I said, and what if something happens to you? We thought about it long and hard. And then we saw the surgeon.

You were at the University Hospital in Zurich?

Yes, with the surgeon, Mr W. And he said, you should do it as soon as possible.

He said that?

Yes he advised me to. That was what I should do, the sooner the better. He explained the pros and cons, mainly the pros actually. And I thought, well, if she wants to. So I agreed to it. Then she had all the necessary tests done. She was in hospital for about 2 days.

And why were you initially against the idea?

Well, I don't know if I could have handled it if something had happened to her during the operation. I mean, there's always a risk with surgery. Or if she'd had complications afterwards, and I'd recovered. That was going through my head.

And what made you agree to it after all?

I know my wife, she's so selfless. She'd have done it for her brothers and sisters as well. She'd rather starve so that others have enough to eat. So I realized, she needs to do this. She wants to. She'd suffer if she wasn't able to help me. And then she had the tests done. We got the OK and the date was arranged.

I'd just like to ask a bit more about these tests. You and your wife both had physical examinations. But then there are the discussions as well, with the psychiatrist for instance.

Yes, he wanted to know whether I was putting her under any pressure.

How did they ask that?

In a sort of roundabout way, but they realized immediately that it couldn't be like that in our case. She said immediately that she had suggested it and that I'd been against the idea. So that was clear from the start, that there was no pressure from my side. It was my wife's own idea.

Would it have been easier for you to accept an organ from a brain-dead donor than from your wife?

No, it's not that. I was just worried that something might happen to her. I was haunted by that idea. After that talk, I realized that there is a risk, but that it's not very high. There's also a risk of having a road accident or falling down the stairs.

And then you had your operation? What was the hospital care like for you and your wife? You told me earlier in the car that people always just concentrate on the recipient.

That's right. We were very satisfied.

And your wife?

She was, too. Fortunately we were both in the same room. That was ideal. I have no criticisms at all. But of course it's always a matter of opinion. For me everything was fine, and for my wife too.

But I understand you had some problems afterwards?

Yes, we were discharged, my wife two or three days before me, then I came home. Everything was fine. And then you forget to take the stuff.

You forgot to take your medicine?

That's right. I think it was the CellCept. I had one of those boxes, a pill box with the doses for each day. And the Sandimmun is quite big, there was no room for it, or for the CellCept either. So I put them out separately. And then I only took the Sandimmun and not the CellCept. It was only for about a week. On the Sunday I was watching a cycle race, and I suddenly felt very hot. But it wasn't a hot day at all. It was

like suddenly catching a cold. Then my head was splitting. The next morning I didn't have any appetite. So I thought, something's wrong. I also started putting on weight straight away. I noticed that I couldn't pass water properly. Fortunately I had an appointment soon after that. I was vomiting too, and then I realized that I hadn't been taking the CellCept. I suddenly understood what was causing the problems. Then my creatinine was 500. They kept me at the hospital. This OKT3 therapy, it's a very powerful drug, have you heard of it?

Yes.

I was given the first dose in intensive care. It shook me a bit, but it was OK. Then I got the next six on the ward. But for a week nothing happened. I was getting heavier and heavier by the day, up to 76 kg, I put on almost 1.5 kg. I was virtually unable to pass water.

And how did you feel about having made a mistake yourself?

It's funny. It didn't really make an impression. Otherwise I always get upset if I do something wrong. If I see it's my fault. And of course it was obvious whose fault it was, but somehow I saw it as fate. It just happened.

And your wife?

Well, she certainly suffered, much more than me, when she came to visit me. I wasn't able to eat, a couple of bites and that was it. It was like the way it had been during dialysis. Then I was hungry too, but after a couple of bites I couldn't get any more down. But of course this was much more abrupt, it happened overnight.

And did your wife blame you?

Only herself if she blamed anyone, she could have checked as well.

Oh, she blamed herself?

Yes, "I could have made sure you took your medicine as well," she said. But what's the use, it just happened. I was convinced I'd manage again.

But you didn't blame each other?

No.

She was just worried about you?

We should never have done it, she said.

What did she mean by that?

If we hadn't given you a kidney, you wouldn't have been here again now. I said, that's got nothing to do with it. It just happened.

She called the transplant into question again?

Yes, because she saw I was in a much worse state.

Even worse than while you were on dialysis?

Yes, yes definitely. With OKT3, I was really dopey. I was tired and I always had these dreams in the night. It was like being feverish. I just wasn't able to eat. In the morning I had to force myself to have a bite.

But you didn't feel guilty towards your wife?

No.

So for you it was like fate?

I'm sure I didn't ever say anything like that to her. She didn't have anything to do with it. It was purely my fault. I couldn't say she was responsible for me not taking my pills.

When you were admitted to hospital again and back on dialysis, didn't you feel guilty towards your wife?

No, not really. Well, yes somehow, perhaps a bit. I can't really say now. For me it was just like fate.

And your wife didn't take you to task?

No, not at all, neither of us blamed the other. Of course I'd have had no reason to. All she said was that she should have made sure as well that I took everything. At first, she did check and ask me. And then that particular week she didn't. We even went for a walk one evening, and I took the pills with me, but only those two. But she didn't notice either. She watched, I had to take them at eight o'clock on the dot, every twelve hours. And I just took the two Sandimmun but not the CellCept. But she didn't notice that either.

So she blamed herself?

Yes, but there's no point, it's too late. You can't turn back the clock, I told her. Things can only get better. Yes, that's how it was.

Yes, but you said earlier on that your wife had once said, "I shouldn't have done it after all," because your condition was worse than before?

Yes, when she saw me suffering, when I wasn't well during the OKT3 therapy. Then she did say, I shouldn't have done it, then you wouldn't be in such a bad way now.

Even dialysis would have been better?

Yes, at that moment dialysis would certainly have been better. But then I said, it'll be OK. It's just temporary. It'll take a little while. The doctors always said so too.

Has your outlook on life changed since the transplantation?

Yes, maybe I've become more egoistic, and I can see that you can do much more than you might think at first.

In what way egoistic?

I feel the success of the transplantation is my own achievement. Because I'm basically someone who thinks positively, it worked out. Of course I'm grateful to my wife, but I don't for instance feel any gratitude to a higher being. There are celebrities who talk about a new relationship to God after an operation like that. That doesn't apply to me.

I don't think I'd have been as selfless as my wife either. I'd probably only have donated my kidney to her if I'd seen her suffering on dialysis.

Mr M., many thanks for talking to us.

5.2 Mr S., recipient

A patient who received 60 per cent of his sister's healthy liver after suffering from hepatitis C and liver cancer was interviewed by Christoph Rehmann-Sutter.

Could you tell us how you came to require a transplant?

Mr S.: I got hepatitis C when I was in my early twenties and since then I'd always had increased liver enzyme levels. At the end of the 1980s fibrous tissue was detected in a liver biopsy. Later, in an ultrasound scan, a nodule was discovered, which turned out to be a tumour. And then we had to move fast.

How did the time factor come into it?

My blood group is O, with an average wait of over a year for a cadaveric liver. People with blood group O can donate to any other group, but they can only receive O themselves. So there was an indication for living donation. I had to be put on the waiting list, as that's one of the conditions for living donation. My brothers and sister all immediately said they were willing to donate. In that way, I'm lucky to have a family like that.

How did you feel about this new situation?

I was already in a very bad way and of course my brothers and sister knew that. I was thinking about the financial aspects, but also asking myself: Is it worth it? What risk am I taking? But when that was all clear, I told them. They reacted in different ways, but they were all prepared to be a donor.

You said you thought about whether you even wanted to proceed? What would the alternative have been?

The alternative would have been "dying". At that time I was also taking an interest in complementary medicine and the issue of confidence in one's own body. The question that arose was whether

deciding to have a transplant was a vote of no-confidence in myself. It's interesting that the fear-of-death business was always associated with the operation. Experiencing my life gradually slipping away wasn't actually such a big thing. That's something you're already familiar with.

And the operation? Did you take a rational approach to that?

I read up about it on the Internet and got information on various aspects from the University Hospital. From my point of view, they made an excellent job of informing donors and recipients. On the day before the operation, we were able to have a look at everything, too – the intensive care unit and the operating theatre. I also had psychotherapy beforehand, as a way of preparing myself. I think that all went fairly well, actually.

Was it already clear during the preparations which member of your family was to be the donor?

The University Hospital recommended that we should decide amongst ourselves. The first step is a three-day assessment you have to undergo. And then the first suitable candidate is chosen to be the donor. My youngest brother was eliminated after these tests, but my sister turned out to be suitable. My sister was assessed in March and then the operation was in May. The whole process took over 5 or 6 months. And during that period there were a lot of preparations; we talked to each other a lot, the day before the operation we had a party. My sister and I tried to resolve difficulties with a lot of laughter, with a party, but there were tears as well of course. We cried a lot, we're good at that...

And after the operation? Then there was quite a difference between the situation for you and your sister, wasn't there? She had half a liver less?

A peculiar relationship of gratitude develops, which can even become unhealthy. My sister once told me to my face that I should give the thanks a rest: "It's over, it's your liver now and that's it." What should remain is concern for each other.

In other words, the transplantation isn't over when the organ has been grafted. The subsequent emotional processes seem to be just as important, in becoming a "whole" person again.

After the operation I had a strange experience. I was with my girlfriend at a dance session, expressive movement. I didn't feel good, but I didn't know why. And suddenly I had the idea of phantom pain, I felt a void, like the yearning of the body for the old liver. But I also once felt as if my liver was yearning for my sister. It's confusing. It's not quite schizophrenic, but somehow it's like being split in two, it's quite traumatic. You've got to work on yourself, and you've got to take these things seriously, take them on board, I think that's important. And you've got to be alert. Otherwise you can sink into depression.

The donor's wellbeing is probably another factor, isn't it? If she had had complications?

I can only say hypothetically, as everything went well. But for a long time she said she still wasn't feeling a hundred per cent. And every time it bothered me. You do feel responsible for her. At the beginning she had the problem that she didn't tolerate the morphine. Then she had to take an alternative painkiller because she felt sick the whole time. She felt sick all day. I agonized about whether I wasn't to blame for her condition.

There's also the financial side, isn't there? The health insurer isn't paying for it?

I wanted everybody concerned to be informed. But then my health insurance company refused to cover the costs because the operation isn't on the list of reimbursable procedures. At the time of the operation the question of coverage was still completely open.

And after the operation?

During the rehabilitation period the situation was still unclear. But there was then a very intense public debate about the issue of funding for this type of operation, also on television. While the health insurers still refuse to cover the costs, an inquiry has to be made to the cantonal authorities under an approval procedure for each operation. And before the approval procedure, we – two recipients and two donors – wrote a letter describing our positive experiences with this operation. We believe that it really is a good treatment, particularly if it's urgent, and it's actually also very favourable in terms of cures. The discussions about the financial aspects had an effect on me. I became actively involved with this issue. For me it's also a matter of vitality. If I just lie around recuperating, then I'm not living, am I?

From your experience, are there any points or services that should now be improved. Were you dissatisfied with any aspects of the care provided?

From my point of view, it really went pretty smoothly. I think there needs to be a clear separation between the donor's situation and the recipient's situation so there can't be any kind of exploitation. It also needs to be clear to the family that an organ donated has to be written off, that it can't be repaid with gratitude.

One criterion included in the draft Law is that the decision has to be freely taken. But what's it like in practice? In a specific case, where someone might be facing death – can it possibly be "voluntary"?

I see it as a dynamic process. If I imagine asking my brother about living donation, and he decides as soon as I tell him, then that's not a voluntary decision, he's controlled by the situation. There would need to be, say, therapy provided, or a certain time would need to elapse. The people concerned also need to be involved, for example the partner or the children. One of my brothers said yes on the spot. My sister also agreed very quickly, the other brother thought it over for

two or three weeks. They handled the voluntary decision in quite different ways. It depends on people's character. It could be controlled a bit, for instance by making therapy a requirement, to provide psychological support for the decision-making process.

Did a situation arise where you thought you needed to help the donor make a voluntary decision? Were you involved in that? Did you just say, I need a liver, and then leave the decision up to them? Or was there more to it than that?

A lot happened before the decision was taken. Earlier on, for example, I had a daydream where I was sitting on a table with my sister, naked, exchanging an organ, before I even knew about the transplantation. That really was a weird vision of the future. Intuitively, I chose her as my preferred candidate. And you also have to deal with the idea of a cadaveric liver. It was of course always possible that one would suddenly materialize after all. I could cope quite well with the idea of living donation, apart of course from the risk of death associated with the operation. But cadaveric donation, an organ from someone who's just died, that was a strange idea. One time there was a group of us discussing it and four of the eight people present had a donor card. I asked them about their motives and they all answered that they'd be glad if they could live on in another person. And that helped me. I thought this idea of sharing life was very nice.

I've asked you everything I'd planned to ask. Maybe there's another point you would like to make?

It seems to me to be problematic if donation involves partners, rather than brothers and sisters, because then of course they'll always have to come to terms with the feelings of gratitude. A sister goes off and leads her own life again. But if you live together, very close, then it's highly problematic. I wouldn't recommend that myself. My ex-wife also had the same blood group, but she was too frightened of the operation. For me it was also quite clear that she wasn't a candidate, just because of the way I saw partnership. Of course, if there's no other option, you'd also have to consider that, but then you'd have to have the necessary support, maybe couple therapy.

Was that already clear before you asked your brothers and sister?

Yes. It was a complicated time, where there was a lot to be worked through, within the relationship as well. The thought of the operation was very stressful for her, and then she said she was frightened. She asked me whether I expected her to do it. Fortunately she asked the question. Of course I immediately said no, for the reason I just mentioned. I also think it's important, even if living liver donation becomes routine, for people always to prepare themselves properly for it.

You need to ask yourself about potential problems of dependency and possibly have therapy.

Mr S., many thanks for talking to us.

5.3 Ms S., donor

This woman, who donated 60 per cent of her healthy liver to her brother, herself works in nursing and nursing science. She was interviewed by Christoph Rehmann-Sutter.

Could you tell me from the beginning how it all came about?

Ms S.: My brother has lived with hepatitis C for a long time now and over the past 2 years things got progressively worse: the usual sequelae, liver cirrhosis and later a liver tumour as well. And then the question of living liver donation first came up. It was suggested to him at a check-up and he subsequently approached us. Straight away, all three siblings said they would be prepared to donate. We then met up to discuss everything. In a family it's not just one person who donates in isolation, there's a whole family and everyone has some part to play.

At this meeting we decided on the order in which the preliminary assessments should be done: the youngest first. But my brother wasn't suitable. And then it was my turn. I went through all the initial assessments and was found to be a suitable donor.

Was the option of saying "no" actually available at any point in the decision-making process – was it possible even to consider it?

I could certainly have said "no". But it's a very difficult situation. I've never been so frightened in my life. I analysed the literature, studied all the mortality rates and asked myself whether I could really justify it in view of my own family. I had to answer a lot of questions. The answer "yes", which was initially quite spontaneous, motivated by affection, was tested many times, by myself and others. And every so often I'd ring my brother and tell him that it was difficult for me and that I was frightened – and that was OK. The question was which decision would be easier for me to live with ... you have to approach it rationally and emotionally, take personal circumstances into account, talk to experts.

Were you told there was absolutely no question of getting a cadaveric organ? Was the alternative somewhere on the sidelines?

That alternative did exist, but time was of the essence. My brother's condition was deteriorating. We wanted the transplantation to be done fairly quickly, while he was still in reasonable shape. We had the first discussions in December. Tests were performed on my youngest brother in February and on me in March, and then the operation was in May.

Did you have the impression that there were medical reasons for the long wait?

I felt, to some extent, it was ... for financial reasons. My brother and I went into hospital without any precise assurance of funding. I was certainly a bit worried about the finances. But it would have been clear for all of us that we would have borne the costs as a family.

What about any follow-up examinations you may need?

If there were any late effects – for example, cancer develops in about 5 per cent of all liver donors – then I'd have considerable problems.

And what about your loss of income?

I didn't work for 2 months and was generously supported by my Institute. One reason was certainly the fact that at the Institute we have another transplantation programme which provides support for relatives and patients. I could have started work again quite soon after the operation, but there was the fatigue, after all 60 per cent of the liver was transplanted.

And is fatigue still a problem?

I'm not sure. I'm working a bit more than I used to. So now the question is, is it the workload or is it my liver? I don't actually feel any difference. Physically, I'm fine. I'm sensitive to changes in the weather, like other people with a large scar. As far as the liver is concerned, I have a fairly healthy lifestyle, I don't drink much alcohol, I avoid fatty food, I'm aware of what I need to be careful about.

What about the decision-making process – in terms of support and psychosocial assessment. What was your experience? Was anything offered by the hospital? Or do you wish anything in particular had been done differently?

I have an excellent social network and a good family circle, where I find the support I need. I had a discussion with a psychiatrist about whether I had taken the decision independently, but also about what kind of network and support I have. I also received extremely good preoperative information from the doctors. I'm the kind of person who always wants to find out the details. I want to be familiar with the literature, get an idea of things for myself, and I spoke to the doctor; she met me separately on two occasions, made drawings, showed me pictures, compared the results of studies and so on. I'm very grateful that she set aside time for me as well.

The approach taken in Germany, for example, is to convene a committee to review the authenticity of the donor's decision. Would you have welcomed something like that?

I had received all the information and also had time to digest it before my discussion with the psychiatrist. Independence is a very important aspect and to that extent I would strongly support that type of committee. But I wouldn't want to talk to a whole committee, I'd prefer individual discussions with one member of the committee.

You're a nurse yourself: in the living donation process, as regards the liver in particular, is there any aspect of nursing care which is different from other situations?

The administrative staff, the study nurses, are important and supportive because they really asked about how things were in my

family. They were keen to talk and took an interest in all the psychosocial data: "What about your immediate circle?" "Can you make arrangements for this at work?" There really is a big difference of approach between medical and nursing staff, which I often experience in other situations and experienced again in that specific case. The medics were concerned with my liver values, they weren't particularly interested in the psychosocial framework, the effects of my illness on everyday life, the whole system involved, and so on.

That brings me back to the question of your decision. One aspect is of course the risks of mortality and morbidity. Expressed in terms of statistics and probabilities, it's not easy to assimilate. How did you handle that?

I asked the doctor and the nursing staff to tell me about what had happened in other cases, for example, bleeding during the operation. Quite often you're shown data and pictures, but examples of other patients aren't described so much. And I wasn't myself aware of one very important element: the major nausea, due to 60 per cent of the liver being removed. For 2 weeks after the operation I suffered from severe nausea, which I'd never experienced in that form. I mean, the pain is bad and the nausea.

Was it important for you to know your brother's chances of a successful outcome, whether the liver would really "take"? Or the graft survival time?

That was a very important factor, also subjectively. When I woke up after the operation, the first thing I asked was, "How's my brother?" The worst thing for a donor is if the recipient doesn't wake up again. There's also an emotional aspect: the very close attachment. You really almost have to see the donor and recipient as a couple, for a while. We joked together, wisecracking about the traits that had now passed from one to the other. It's totally unrealistic, but it shows the bond between people.

And does this physical bond weaken again?

There were situations where I had problems with the pain and he felt very responsible for my wellbeing. The sense of responsibility is mutual, but it does pass. It seems to me like two individuals who are brought together by this event and then at some point go their separate ways again.

Did he also suffer from fatigue and nausea?

He didn't have the nausea. Of course, his liver function got an enormous boost. He received 60 per cent of a liver which, as it were, worked 100 per cent. Initially, the recipient is normally in better condition than the donor, but that changes again. My 40 per cent was back up to 100 per cent again by the autumn.

Would you regard counselling, follow-ups, etc. as a sign of appreciation and support for donors?

Yes, I'd even say society has a kind of obligation. And I think, if there are more living donors at some point, then we'll have to think about how these people are looked after. What kind of information, advice, support is required? During their time in hospital and rehabilitation? We donors recover pretty quickly. And as soon as the medical process is over, then nobody asks how you're feeling any more. And I think the question needs to be asked: "How are you feeling? What does it mean for you?"

Shouldn't the aim be to have long-term monitoring?

A comprehensive programme would need to be set up. My experience consisted of good preparation, good acute care, poor rehabilitation and a very bad follow-up. That's typical of our healthcare system. My insurance – I haven't got private coverage – wouldn't reimburse any costs. Information on the insurance implications should be provided before transplantation. You've got to be aware that there are consequences for the donor which the medical system doesn't want to be responsible for.

I think another general point is important for any comprehensive care programme: if you only concentrate on the recipient or the donor, that's an isolated view. The aim should be to establish a combined recipient-donor programme. Involving relatives too, very careful and comprehensive, that would be a wonderful care and research programme, that would be fascinating!

Ms S., many thanks for talking to us!

6 – Background: the medical perspective

6.1 – Psychosocial evaluation

Professor Alexander Kiss, Chief of the Division of Psychosomatic Medicine, University Hospital, Basel, was interviewed by Christoph Rehmann-Sutter.

Professor Kiss, how are you personally involved in living donation?

I'm involved in the psychosocial evaluation of potential living organ donors. In the case of men and women who wish to donate a kidney, I provide a second opinion. The routine psychosocial evaluation prior to organ removal is carried out by a colleague, who is a clinical psychologist. I'm also primarily responsible for seeing all the men and women who wish to donate part of their liver, although the operation itself is performed not in Basel, but in Geneva.

What's the actual procedure for a psychosocial evaluation of this kind?

Essentially, it consists of an in-depth discussion. This includes questions about the donor's relationship with the potential recipient, the decision-making process and the psychosocial history. At the start of the meeting, I explain to the donor that my function is not primarily to hinder or prevent the planned transplantation, but to establish whether legal responsibilities have been fulfilled, and whether any problems are foreseeable that may occur after the operation. I try to be the donor's "advocate". For this reason, during the assessment, I need to speak to the potential donor alone. But for me it's also important to speak, not only to the potential recipient, but also to the donor's partner, as they are also affected by the decision to donate. At the end of the meeting, I summarize my impressions and draw attention to any difficulties that may exist, and also to anything that is still unclear to me, for which a further appointment is required. We also routinely carry out a number of standardized tests involving questionnaires.

Does this discussion influence the decision to donate an organ?

We need to remember that there's also a decision-making process for the recipient. Most donors make a snap decision when they're confronted with the patient's obvious need. They know very quickly that they wish to donate. Only rarely is it a rational process of weighing up the pros and cons. So actually their decision has already been taken before the counselling session.

This talk is more concerned with how donors can cope with the decision and its consequences in the future, and what could happen. They're better prepared for the possible outcomes and have a better idea of what they're letting themselves in for.

In the course of the assessment, many recipients also ask the donors to reconsider their decision, and not to donate. It's not easy to accept this enormous gift. We humans are, of course, genetically designed as if we were to have the desire to return someone's kindness. With organ donation it's just not possible to reciprocate.

Would you actually be able to stop the whole process? In other words, would your opposition be binding? Could a highly motivated donor circumvent it and donate an organ in spite of this opposition?

Yes, my opposition is binding. It's rare, but it would be necessary in a case of psychosis, where the donor's judgment is impaired, or in a case of marked depression. For example, we once had a case where

after the assessment I advised a prospective donor to undergo treatment for depression before making any decision on donation. As a result, the patient's name was put on the waiting list for a cadaveric organ. An organ was then found and the patient received it; so, in this case, living donation was not carried out. It's important to point out that, from my point of view, a patient with a successfully treated depressive disorder, i.e. someone who is not currently depressed, would certainly be suitable as an organ donor.

What role does psychosocial evaluation have to play? How would you describe its function?

I see it primarily as counselling for the donor. Donors have to act in a difficult situation, where they're often under pressure. That's completely unavoidable. Pressures are created by the fact that the patient's life is at risk, by the opportunity the potential donor has to save it, and by family expectations. But one can cope with these pressures more or less well. This inevitable pressure is to be distinguished from active efforts that may be made to coerce a donor. Such attempts, should they occur, should not tip the balance, but they are another difficulty that has to be coped with. I see it as my role to provide support in this type of situation so that donors can take their own decisions – which is no easy matter in individual cases.

How can the risks be explained? They vary widely, don't they, depending on the organ concerned; different risks would arise for kidney donors than for liver donors.

Yes, the risks vary from one organ to another. What's involved is not only the risk of dying as a result of the procedure (which is extremely unlikely with kidney donation) but also the risk of suffering postoperative complications. Thanks to the Swiss Living Donor Registry, we're able to tell donors in advance how high the risk of temporary health problems after kidney donation actually is.

From your point of view, when would living donation be psychosocially contraindicated?

There are only a few absolute contraindications, e.g. if a donor is suffering from acute psychosis or if it's clear that the potential donor has only consented to donate as a result of external pressure, although he doesn't actually want to himself. Donation is also to be rejected if there are grounds for suspecting that the motivation is not an emotional attachment, but a financial interest. That would contravene the current legislation. Examples of relative contraindications would be difficult and ambivalent relationships, or cases where the donor covertly expects something in return from the recipient.

Are there also gains for the donor?

That varies from case to case. The satisfaction of having made this type of gift from feelings of love can certainly enhance the donor's self-esteem. In the case of couples who live together, the donor of course also benefits from the fact that the partner is more mobile and less

restricted in terms of quality of life. This means that, for example, it's much easier for them to go away together.

In your view, how could or should the care provided for donors be improved?

The pre-transplant psychosocial evaluation, which in my view is absolutely essential, should be standardized at the various transplantation centres so as to reduce the risk of differing assessments. After organ removal, donors need to be systematically monitored for health problems in the short, medium and long term. Professor Gil Thiel has been a pioneer in this area, with the Swiss Living Donor Registry. This should be extended to cover not just medical but also psychosocial aspects. At present, this type of care tends to be largely a matter of chance. It has been shown to be very valuable to ensure that donors receive sufficient medical and psychosocial attention – rather than focusing exclusively on the function of the graft and the recipient. In the event of complications in the recipient, it would be important to enquire how the donor is affected, as these complications may also place a psychological burden on donors.

What is your main concern regarding regulation in the Transplantation Law?

Switzerland would be well advised to maintain its traditional approach of keeping legal regulations to a minimum. It shouldn't adopt the German tradition of seeking to regulate every last detail in the law. That leads to inflexibility and creates difficulties in individual cases.

Professor Kiss, many thanks for talking to us!

6.2 - Medical aspects of living donation

Jürg Steiger, Basel

In the course of its deliberations on the issue of living organ donation, the NEK-CNE invited a number of experts to attend its meetings. Excerpts from Professor Steiger's responses to the Commission's questions are reproduced below.

Normally, the prospective donor's medical condition is assessed in detail by the GP. The records are sent to the Cantonal Hospital in Basel, where they are circulated to various departments and committees: a psychological evaluation and a nephrological assessment are conducted, and the donor is informed about chances, risks, mortality, etc. In addition, special laboratory tests are carried out, and a dossier is then compiled, donation is approved and the patient is informed of the date for the procedure. The final investigation, visualization of the kidney using a contrast medium, is only performed immediately prior to transplantation. Ideally, the psychosomatic and nephrological assessments should be carried out at an early stage, as they take longer than you think (two to three months may go by before one is actually ready to perform the transplantation), and also to ensure that sufficient time is available if problems arise – for example, if a parent is not from Switzerland and requires a visa to enter the country. There are also situations where the recipient needs the organ urgently, if dialysis is no longer possible, for example.

Would it make sense to introduce a system in which the risks associated with living donation are differentiated, i.e. to define high-risk (e.g. liver and lung) and relatively low-risk (e.g. kidney) procedures?

It's difficult to answer that question. Essentially, equal weight should be attached to the various risks. It's true that morbidity and mortality are higher with living liver donation, but one would have to ask what additional requirements there should be if a risk classification system were introduced – two psychological assessments? There's probably no need for that. A good psychological and medical evaluation is certainly required, but that's also true in the case of kidney donation. The most important element, however, is the information provided!

Are there also individuals in Basel who express a wish to donate an organ anonymously?

Inquiries of that kind are made. There is said to have been a similar case in Geneva, and in Basel the assessment process is currently under way for an anonymous donation; this takes longer than for normal living donation. This case involves an elderly man who wishes to donate and had already inquired at various centres; however, as he never received a response, he approached Swisstransplant. At Swisstransplant, the feasibility of anonymous donation is currently being considered by a medical committee, and this organization tried to act as an intermediary, but that didn't work either. Finally, the patient came to the Cantonal Hospital in Basel. Three expert reports were prepared, and it now looks as if Switzerland's first anonymous donation will take place in August. In the US, the ratio of inquiries concerning anonymous donation to living donations overall has been calculated; the proportion is about 10%, and although this is a small number, it doesn't seem credible to talk about a shortage of organs on the one hand and on the other to turn down – or even refuse to consider – an offer of anonymous donation.

If in the course of the assessment it is felt that voluntariness is not assured (for example, if a parent is exerting considerable pressure on a child), does one then protect the patient by citing medical reasons, claiming that the donor is not suitable, or is that kind of situation dealt with through family therapy?

Recently, a pair of siblings were initially opposed to transplantation. The situation changed, and they finally decided to go ahead with the procedure after all, which was then successfully performed. Although these processes aren't that common, they show that there is always pressure as soon as someone is confronted with the possibility of donating to a family member. That's why there are always one-to-one discussions. If there is some indication during these talks that the donor is not certain, then he or she is told something that's medically relevant – as a kind of excuse. But that doesn't happen very often. One could argue about whether it's ethically acceptable to be untruthful, but the aim is to protect the donor. In addition, donors are always told during the evaluation session that they should contact the doctor if they have a problem. Although the pressure is still there, this does alleviate it a bit.

It's certainly difficult enough, if you just imagine in a quiet moment that you were supposed to donate, for example, a kidney to a sibling or your father, that you didn't really want to because you were afraid, but that you didn't have the courage to say no either.

Are there also situations where patients from abroad inquire whether a transplantation can be performed in Basel; and what happens if people bring along their own donor?

At the Cantonal Hospital, transplantation is also performed in patients from abroad – especially German patients, because for one thing transplantation has developed haltingly in Germany and for another it's not so problematic in a German couple, as the same criteria are applicable there and the same type of evaluation is carried out as in Switzerland; German donors undergo the same assessment process, and the assessment documents are of the same standard.

The Cantonal Hospital in Basel is now receiving more inquiries from foreign patients because since 9/11 it's become more difficult to travel to the US, and you're hassled there. The reality is that a new source of income has opened up for hospital directors; some less well-off university hospitals have sent a delegation to promote their institution. It's problematic in cases where people don't have the same cultural background – for example, if they come from Arab countries – there are language difficulties, and the recipient also brings a donor along – which evidently has happened.

Is the procedure performed if Germans come to Switzerland with friends in order to circumvent the German law?

A crossover transplantation was indeed performed, but the idea was not to circumvent the law or to avoid even making inquiries in Germany. On the contrary, legal opinions were sought in Switzerland and also in Germany, and ethics committees were consulted in Switzerland and Germany. Otherwise, although the possibility of non-

emotional – i.e. purely altruistic or anonymous – donation exists, it is very limited.

To what extent do the risks vary among donors of the same organ? For example, is the range of risks within the living kidney donor population similar to that among donors of other organs? Is it on a comparable scale, or is there only minimal variation between individuals?

The difference in the risks involved is greater between than within organ donor groups. The fact that living liver donation procedures are not paid for in Switzerland is of course connected with the fact that they are comparatively risky; the mortality risk is much higher than with kidney transplantation.

However, it must also be said that the risk varies within an organ donor group – for example, it's unfavourable if a 65-year-old parent has hypotension, and this has already caused damage in the form of slight enlargement of the heart muscle, or if a kidney donor has high blood pressure. In Geneva, a patient who donated a kidney about 15 years ago developed renal insufficiency himself due to hypertension. In the US an analysis was published of the number of kidney donors who subsequently require dialysis. And there are cases, but the incidence is the same as in the general population. The more living donations there are, the more likely it is that something will happen at some point.

Professor Steiger, many thanks for providing this information.

7 – The legal position in other countries (in relation to the NEK-CNE Opinion on living donation)

Georg Amstutz. Summary of "Die rechtliche Regelung der Lebendspende im europäischen Vergleich" [A comparison of legal regulation of living donation in various European countries]

7.1 Introduction

In the area of living organ donation, transplantation laws have two main aims, “namely, to introduce regulations for the protection of individuals exposed to the risk of coercion or exploitation and to establish legal certainty for the entire field Despite their different legal cultures and traditions, European nations approach this matter in a comparable manner. The need for *informed consent* [cf. 7.2], for example ... is either presupposed or – most frequently – quite explicitly stipulated in all laws. This fundamental medical principle of respect for individual autonomy is shared by all European legal systems” (p. 41).

“However, as far as the two central problems associated with living donation are concerned – the issue of the eligible *donor population* [cf. 7.3.1] and that of the *subsidiary status* of living donation vis-à-vis cadaveric donation and other types of treatment [cf. 7.3.2] – one cannot speak of a uniform standard throughout Europe. The range of conflicting national regulatory models extends all the way from paternalistic to liberal approaches” (p. 42).

According to Gutmann and Schroth, the numerous regulations at the European level represent an opportunity in particular to establish greater legal certainty on the “key issues of donor population and subsidiary status” and “to achieve more than merely cementing the lowest common denominator” (p. 43).

7.2 Transplantation legislation in Europe: common standards

7.2.1 Donors' informed consent

One concern is shared by all of the countries investigated in the study by Gutmann and Schroth: all of the laws concerning living organ donation seek to ensure “that informed consent to organ removal has been freely given by the potential donor” (p. 44). However, the density of regulations varies from one country to another. In many countries, the relevant legislation requires that consent should have been given explicitly, freely and consciously. In other countries, the regulations are even more precise, with particularly stringent requirements being placed on the information provided for donors: “... the relevant provisions vary widely internationally” (p. 44). The regulations are thus more or less elaborate, ranging from the requirement “that the potential living donor be duly informed by a physician of the nature, consequences and risks of the procedure” (Denmark, Finland, Italy, Russian Federation, etc.) to more comprehensive specifications, such as those applicable in Spain, “where potential donors must additionally be informed of the foreseeable physical, mental and emotional consequences of donation; possible effects on the donor’s personal, family and occupational life; and the benefits it is hoped the transplantation will yield for the recipient” (p. 44). Similar provisions also apply to donors’ informed consent in France, Belgium and the Netherlands. In the UK, explicit provisions are only included in transplantation legislation for cases of living donation involving

individuals who are not genetically related. All other cases are covered by the concept of informed consent developed for therapeutic procedures (p. 45).

Under Art. 12 b of the draft Swiss Transplantation Law, living donors are required "to have been fully informed and to have freely given written consent". However, provision is made for additional regulations in associated Ordinances: according to Art. 14 Para. 2, the Federal Council is to specify the "requirements for information", in particular, how and by whom it is to be provided.

Throughout Europe, withdrawal from the donation procedure is possible at any time. Regulations to this effect have been passed in numerous countries, and in some cases (France, Spain, Hungary) it is even specified that withdrawal is not subject to any formal requirements. In the draft Swiss Transplantation Law, no explicit reference is made to the possibility of withdrawal since, as mentioned above, informed consent is a universal requirement for any therapeutic procedure.

7.2.2 Recipients' informed consent

"The principle of informed consent or informed choice, also on the part of the recipient of a living donor organ, is firmly established both in common law tradition and also in the Central European legal tradition." In the general debate, recipients' informed consent does not appear to represent a problem in its own right.

7.2.3 Safety and limiting of risks for donors

In almost every country, transplantation legislation prohibits the removal of an organ in cases where donors' safety would be at risk as a result of the procedure. "The principle that removal of an organ must not terminate or pose an immediate threat to the donor's life represents a universal legal standard" (p. 49). Certain countries even attempt to "define risk/benefit ratios" in their legislation (p. 49). "In general, the removal of organs and tissues – especially if they are non-regenerative – for the benefit of a third party is permitted only for therapeutic purposes" (p. 50).

According to the draft Swiss Transplantation Law, organs, tissues or cells may not be removed if this would pose a serious risk to the donor's life or health.

7.2.4 Procedural arrangements

In the various European countries, more or less stringent procedures have been introduced with the primary aim of assessing the acceptability of living donation in terms of indication and permissibility.

These procedures involve a wide variety of authorities, ranging from judges through medical ethics committees to approval bodies specifically established to deal with transplantation matters.

Selected examples

In France, living donation requires not only the patient's consent, but also "legal permission, with consent regularly representing only one of a number of elements required. To this extent, the significance of the provisions of the French Transplantation Law is reinforced and sanctioned by criminal law. This also applies to procedural regulations. Thus, in France, prospective living organ donors are required to declare their consent before the presiding judge ... of the *tribunal de grande instance*, or before a judge appointed by this court; in urgent cases, the senior public prosecutor at the *tribunal* is authorized to receive the declaration. Having checked that the legal conditions for organ removal are met and that the donor has been adequately informed, the official is required to document and countersign the donor's consent" (pp. 50 f.).

In Italy, the legislation on living transplantation provides for a derogation from the regulations that prohibit transactions involving one's own body insofar as these "result in a permanent loss of physical integrity" (p. 51). After a declaration on donation has been issued by a district court judge, "the director of an officially licensed transplantation clinic, having carried out all the necessary investigations, is required to convene a medical committee, including a physician responsible for the donor, to consider such matters as histocompatibility and the existence of a clinical indication for transplantation. The committee's final opinion ... is to be submitted to the district medical officer, who, after reviewing this opinion, is to forward it within 24 hours to the above-mentioned district court judge. The latter is required to decide by decree within three days whether the transplantation should be approved" (pp. 51 f.).

In the UK, explicit requirements were only formulated for cases in which an organ is to be removed from a non-genetically related donor. An exemption from the general prohibition on organ transplants between a donor and recipient who are not genetically related is granted by the Unrelated Live Transplant Regulatory Authority (ULTRA) "if the following conditions are met: ... no payment has been or will be made, and the registered medical practitioner who made the application to ULTRA has clinical responsibility for the donor. In addition, both the donor and the recipient are to be interviewed by a person deemed by ULTRA to be suitably qualified. This party is required to submit a report to ULTRA, indicating that the donor, having been informed in detail about the procedure by a registered practitioner, has freely consented to it, and that this consent was not obtained by coercion or the offer of an inducement and has not been withdrawn. The report must also mention any difficulties of communication with the donor or recipient and explain how such difficulties were overcome" (p. 52).

According to the first draft of the Swiss Transplantation Law, each individual case was to be reviewed by the relevant cantonal ethics committee. This provision was omitted from the second draft.

7.3 Main problems

In the view of Gutmann and Schroth, the main problems associated with living organ donation concern the eligible donor population and the subsidiary status of living donation vis-à-vis cadaveric donation. "The range of conflicting national, international and supranational regulatory models extends all the way from paternalistic to liberal approaches" (p. 54).

7.3.1 The problem of donor eligibility

7.3.1.1 Minors and individuals lacking capacity to consent

From their comparison of national laws, the authors conclude that the provisions applicable in most of Europe which stipulate legal majority as a self-evident requirement in addition to the capacity to consent to living organ donation "are sensible" (p. 59). Apart from this general prohibition on the removal of organs for the benefit of third parties, procedures that also make provision for donation by minors in exceptional cases could "facilitate more appropriate management of isolated cases involving special circumstances But such cases are unlikely to occur in significant numbers in the context of stringent procedural regulations However, the fact that minors are particularly susceptible to manipulation and exploitation justifies the application of the age limit specified for majority" (pp. 59 f.).

"The regulatory model originally proposed in Switzerland is now also favoured at the European level" (p. 59). In the initial draft of the Swiss Transplantation Law, donation of regenerative tissues or cells by individuals lacking legal capacity or mental competence was to be permissible only if the recipient was a sibling of the donor. In the Submission concerning the Transplantation Law dated 12 September 2001, parents or children of the donor were also defined as eligible recipients. However, this would be subject to the consent of an independent authority, such as a civil court or legal guardian.

7.3.1.2 Eligible population of adult, mentally competent living organ donors

With regard to the "most fundamental issue relating to living organ donation, the definition of the eligible population of adult, mentally competent living organ donors", the authors detect no common standard at the European level. While it was originally immunological reasons which dictated that only individuals with a close genetic relationship to the recipient were eligible to act as donors, the main constraint since the advent of successful immunosuppressant therapy has been the third of the World Health Organization's Guiding Principles on Human Organ Transplantation, "which, in order to

discourage living unrelated donation, also proposes as a general rule for the transplantation of non-regenerative organs and tissues that donors should be genetically related to the recipients... This principle, which even at the time of its origination no longer reflected the state of the international ethical debate, was necessarily formulated primarily with the problems of the many developing and emerging nations in mind and could not claim to offer an appropriate regulatory model for Western European countries" (pp. 60 f.).

Analysis of the various legal arrangements revealed a variety of arguments, but none was found to be compelling or to "justify the exclusion of unrelated individuals from the eligible living donor population" (p. 61):

- a) "Recent studies indicate that there is now practically no difference in the medical outcome of transplantations involving related and unrelated living donors Organ transplants from donors who have close emotional ties to the recipient but are not related either by blood or by marriage are comparatively successful." (p. 61)
- b) "At the same time, there is no evidence to suggest that as a general rule the potential for coercion is greater with unrelated individuals – spouses, unmarried partners, or close friends – than with donors who are family members." (p. 62)
- c) The general exclusion of emotionally related individuals "from living donation in connection with the goal of preventing commercial transactions is quite evidently unnecessary." (p. 62)
- d) "If one assumes that respect for the autonomy of adult individuals entails that their medically informed decision to donate an organ to a relative should also be respected, it is difficult to understand why independently taken, altruistically motivated decisions by unrelated individuals to donate an organ to someone close to them should not be respected as such." (p. 62)
- e) "Also of relevance is a sociological finding. In Western societies, we are experiencing ... not only a process of individualization and pluralization of forms of life but also an erosion of traditional relationship patterns, which are being replaced, particularly in urban settings, by forms of 'post-traditional solidarity ties' in self-established networks. This means that the group of people whose solidarity individuals can expect to enjoy and to whom they themselves feel obliged and motivated to show their solidarity coincides less and less with the group of people to whom they are genetically related." (p. 63)

"For these reasons, a policy of general exclusion of unrelated donation appears to be ill-considered It can be concluded that the line dividing ethically acceptable from unacceptable organ donation does not pass between related and unrelated donors. Rather it cuts across both groups. With donors from either group, there may be factors in individual cases ... that make organ donation appear to be ethically or legally unacceptable Internationally, therefore, only a small number of countries adhere to the restrictive WHO guideline" (p. 63).

7.3.1.3 Restriction-based models

Gutmann and Schroth divide European systems of legislation into three types of regime, "according to the nature and intention of the restrictions on donor eligibility" (p. 64):

- Highly restrictive:
 - the French legislation provides an example of a highly restrictive system. In 1976, living organ donation was still generally permitted; in 1994 the so-called bioethics law was adopted in the *Code de la santé publique*. "Since then, French law has required the recipient of a living donor organ (with the exception of bone marrow) to be the donor's parent, child, brother or sister. Transplantation between spouses is only permitted in an emergency" (p. 64). These regulations are currently being revised. The aim is to "incorporate the idea of safety based on procedures" (p 66).
- Moderately restrictive (two models):
 - a) The first model: "... restricted, but relatively broad definition of the potential donor population, which is however stringent and makes no provision for exceptions ..." (p. 66). For example, the German law excludes "not only altruistic donation of an organ for the benefit of a stranger but also a whole series of other unusual, but ethically defensible models of living organ donation..." (p. 65) – including crossover transplantation.
 - b) The second model: "... a more narrowly defined standard population of potential donors, but supplemented by procedural arrangements for other constellations..." (p. 66). The UK regulations can be assigned to this category: "The prohibition on living organ donation between individuals who do not demonstrably have a close genetic relationship is however not absolute, as the British law includes provisions enabling legal living organ donation to be arranged for other individuals. This facilitated the introduction of the Human Organ Transplants (Unrelated Persons) Regulations in 1989, which ... established the Unrelated Live Transplant Regulatory Authority (ULTRA) as an approval body and specified the conditions under which ULTRA may grant exemptions from the general prohibition on living donation by a non-genetically related donor ..." (p. 67).
- Non-restrictive:

"Most European countries do not impose any general legal restrictions on the potential donor population." Of particular interest are those countries "that have recently resolved, after debating the issues, to refrain from legislating on this specific point" (p. 71).

This also applies to the draft Swiss Transplantation Law, which deliberately eschews "any restrictions on the potential living organ donor population" (p. 72) and "permits ... both altruistic third-party donation for an unknown recipient and crossover transplantation" (p. 73).

“While some years ago one could still speak of contrasting trends with regard to European countries’ laws on the potential living organ donor population, in 2001 a consistent European trend can be detected opposing stringent restrictions of a general character on donor eligibility” (p. 73).

7.3.2 The problem of the subsidiary status of living donor organs

“The subsidiary status of living donation is currently discussed under two headings and advocated by a number of countries and international organizations. The first problem is that of subsidiary status vis-à-vis cadaveric organ donation, i.e. whether living donation should only be permitted when no suitable cadaveric organ is available or likely to become available within a reasonable period of time. It is sometimes additionally demanded that living donation should only be carried out when all other treatment options have been exhausted This is also a question of subsidiary status, i.e. vis-à-vis alternative treatment modalities” (p. 76). The background to this discussion is the principle formulated by the WHO in 1990, which stated that “organs for transplantation should be removed preferably from the bodies of deceased persons” (p. 76).

In most European countries, no regulations exist concerning the subsidiary status of living donation. In Switzerland, the clause dealing with the question of subsidiary status was omitted from the revised draft law. “It was argued that the rule lacked justification since better outcomes were to be expected with living donation than with cadaveric organ transplantation. The concern was also expressed that this regulation might lead to the suspension of all living donor organ transplantations, as a cadaveric organ would theoretically always be available if one waited long enough” (p. 79). In the Submission, the only remaining reference was in Art. 12 d: “Organs, tissues or cells may be removed from a living person if ... the recipient cannot be treated by any other method providing comparable benefits.” The Federal Council may further specify the alternative methods in question – “although it has already indicated that this criterion is not met by dialysis, for example” (p. 79).



Nationale Ethikkommission im Bereich Humanmedizin
Commission nationale d'éthique pour la médecine humaine
Commissione nazionale d'etica per la medicina
Swiss National Advisory Commission on Biomedical Ethics

Opinion no. 5/03

Living-donor partial liver transplantation: the question of financing

The first successful transplantation of a liver lobe from a living donor to her son was performed in 1989. The procedure has been carried out routinely in Asia since the 1990s, and it has also become more common in the US since 1998. In Switzerland, about 20 operations of this kind have been performed at the transplantation centres in Geneva and Zurich since 1999. Usually, the larger of the two lobes (60% of the liver) is transplanted. Within a few months, both parts are restored to the normal size through regeneration. Current empirical data indicate that the morbidity rate (incidence of complications) in donors is non-negligible, although it varies from one country to another, and there have even been individual cases of death. Most donors are family members.

Living liver donation is an expensive treatment, with costs amounting to CHF 160,000 per transplantation. In Switzerland, it is currently financed by the cantons and not by the health insurers. The decision not to include this procedure on the list of reimbursable items was defended on ethical grounds. The main ethical issues concern the risks involved for donors and the potential for moral pressure, which may arise within family relationships as a result of the urgent need for transplantation. The topic of living donation was considered by the NEK-CNE in connection with the current parliamentary deliberations on the Transplantation Law drafted by the federal government.

The question addressed to the NEK-CNE by the Federal Office for Social Security (BSV) and the Federal Commission on Fundamental Principles of Health Insurance (EGK) was whether the particular characteristics of living liver donation give rise to ethical reasons why the procedure should not be included on the social health insurers' list of reimbursable items.

Considerations

In view of the risks to the health of partial liver donors and the potential for pressure, society has an obligation to protect such donors. This could even involve protecting donors from themselves, since consent to donate could be prompted by an excessive, self-sacrificing sense of responsibility for someone close to the donor, with personal risks being accepted without due reflection. The possibility of a life-threatening disease being successfully treated with the aid of an organ donated by a relative creates a situation in which the patient is dependent on the relatives who are potential donors.

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The latter are vulnerable to the extent that they often see themselves as “having no alternative” but to consent, for moral reasons; their refusal would directly endanger the patient. However, the protection afforded to potential donors cannot consist in a denial of their autonomy, i.e. preventing them from deciding for themselves whether or not to donate. Ultimately, each individual is responsible for his or her own life – responsibility cannot be delegated. Accordingly, only the individual concerned can decide whether or not he or she is prepared to consent to living donation, although the decision should be taken on the basis of the fullest possible explanation of the implications and consequences. The protection of donors concerns not only health-related aspects but also their moral integrity.

It would therefore be preferable to establish a system that helps the individuals concerned to make reliable, authentic and considered decisions, taking account of the risks and consequences. Statistically speaking, the risks of liver donation are higher than those associated with the donation of other tissues and organs, such as bone marrow or a kidney. However, it is not possible to express the highest ethically justifiable level of risk in terms of a general formula. Decision-making processes should be designed in such a way as to enable the risks to be responsibly evaluated in individual cases and considered from various perspectives.

The benefits for the recipient and the risks for the donor are not comparable or commensurable. For example, it is not clear how the additional years of life gained can be offset against the risks incurred by donors. These are two quite different things. A subjective evaluation needs to be made from the donor’s viewpoint. Benefits might also include, for example, the significance of the donation for the donor in the context of emotional relationships and the donor’s conception of the good life.

An important, indeed indispensable, condition for potential donors’ decision-making process is that it should be voluntary, i.e. free of coercion or attempts to exert pressure. Organ donation must not be the subject of commercial dealings; this is an unequivocal requirement of the draft Transplantation Law.

Opinion

- 1. There are strong ethical arguments in favour of including living liver donation on the social health insurers’ list of reimbursable items.**
- 2. For living liver donation to be conducted responsibly, supporting measures need to be offered which help those concerned – primarily the donors and recipients – to arrive at a reliable, authentic and considered decision.**
- 3. The costs involved in the preparation, treatment and appropriate aftercare of donors – including treatment of any late effects of organ donation – should be borne by the recipient’s health insurer.**

Statement of reasons

The problem is not resolved by the insurers’ refusal to finance living liver donation since the operation is not thereby prevented, but the associated costs would be privatized. The families who through donation already make an exceptional contribution would feel obliged for the same moral reasons to accept the financial consequences. Moreover, the operation could not be contemplated by poorer families.

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For both reasons, the non-financing option would be open to the charge of injustice. Risks that are voluntarily accepted by donors in a spirit of charity cannot be adduced as a reason for relieving oneself of the costs. In addition, there are ethical reasons why the assessment of whether diseases deserve to be treated should not be based on the different levels of costs involved. The fact that the procedure is expensive should be a secondary factor in the decision on reimbursability. The costs of other expensive treatments are also borne by health insurers.

This Opinion was not based on considerations relating to the allocation of scarce resources. The NEK-CNE is aware that it is not feasible to finance everything that is medically possible. However, in order to discuss the question of allocation, other expensive treatments would also need to be systematically reviewed. The criteria for decisions of this kind must be transparent. In addition to costs, consideration should also be given to urgency and the success of treatment in terms of gains in quality of life.

The NEK-CNE has formulated a number of criteria for accompanying measures. The central concern is to ensure that donors are fully informed about medical and psychosocial aspects before they give their consent, and that comprehensive medical, nursing and psychosocial care is provided in the decision-making process prior to and also during and after removal of the organ. Aftercare should be available for the rest of the donor's life, and any costs arising as a result should be borne by the insurer of the recipient, on whose account the entire procedure is of course undertaken. If these measures can be implemented in the form of an interim solution before the Transplantation Law enters into force, there are, in the view of the NEK-CNE, no ethical reasons why the operation should not be included on the list of reimbursable items.

Conversely, there are strong ethical arguments in favour of granting the operation reimbursable status. Compared with the situation for living kidney donation, the failure to finance living liver donation gives rise to unacceptable discrimination. Whereas a therapeutic alternative exists to living kidney donation (dialysis), there is no such alternative to living liver donation. In addition, the liver is regenerative. Transplantation of a living donor liver lobe can be life-saving. There are not sufficient organs from brain-dead donors to enable everyone who requires a transplant to receive such treatment in good time. Equally, the protection of donors – which is not directly essential to the success of treatment in the recipient – could be more readily assured if the procedure were recognized by the health insurers.

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