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Medical-ethical guidelines: Living donation of solid organs

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I. Preamble

Organ transplantation is a well-established and effective treatment, which increases the life expectancy of organ recipients and improves their quality of life. Along with post mortem donation, living donation provides another opportunity for the patients concerned to obtain an organ, such as a kidney or liver. Living kidney donation obviates the need for a waiting period of several years, during which dialysis would be required. In addition, organ transplants from living donors generally offer greater prospects of success than deceased-donor organ transplants, as they can be more readily planned. For these reasons, living donation is now regarded as the best treatment option. At the same time, thanks to living donation, more organs are available for patients on the waiting list.

With living donation, a surgical procedure is carried out in a healthy person (the donor) for the benefit of another person (the recipient). The risks for the donor depend on the organ donated: the donor is not only exposed to the risks associated with any surgical procedure, but will possibly also have to bear longer-term consequences of organ donation. Living donation thus involves particular ethical challenges.

Like any other interventions affecting personal and physical integrity, organ removal is only permissible with explicit consent. The donor must therefore be fully informed and, in particular, efforts to pressurise a potential donor must be ruled out. Unlike in the case of a therapeutic intervention, the donor's consent and the potential benefits for the recipient are not in themselves sufficient to provide ethical legitimation for living donation. It must additionally be ensured via psychosocial and medical assessment that adequate protection and aftercare will be available for the donor. This may also mean that donation has to be refused in individual cases.

The removal of organs from living persons is regulated by the Transplantation Act[1] and the implementing ordinances. The present guidelines are based on the currently valid legal framework and take account of the most recent developments in the field of living donation (e.g. cross-over living donation). They provide support for medical professionals in the conduct of living donation procedures, focusing in particular on the ethical challenges associated with the donation process.

II. Guidelines

1. Scope

The guidelines are applicable for the removal of solid organs (kidney and liver[2]) from a living donor for purposes of transplantation. They are addressed to physicians, nurses and other professionals who support (potential) donors during the assessment and donation process, and who provide aftercare following organ donation.

2. Basic ethical assumptions

Living donation represents a special ethical situation, as it involves a healthy individual consenting to an intervention in order to donate (parts of) an organ to another person. Of fundamental ethical relevance here is an understanding of the relationship between donor and recipient (cf. Section 2.1), but also of the unavoidable beneficence/avoidance of harm "paradox" (cf. Section. 2.2). Also to be emphasised are the voluntariness of the wish to donate (cf. Section 2.3) and considerations of equity for donor and recipient (cf. Section 2.4). In addition to these basic ethical assumptions, the donation process raises numerous important questions relating to professional ethics, which will be considered in more detail in subsequent sections.

2.1. Relationship between donor and recipient

Without an organ donation, the recipient's health, quality of life and life expectancy will be impaired. Donor and recipient thus stand in a relationship which may also trigger moral feelings of guilt. It is important both to take into consideration the vulnerability of the potential recipient and to ensure the autonomy of the decision to donate. The (recipient's) subjective sense of "dependence" is further reinforced by the burdens assumed by the donor in the course of the donation process/surgical procedure. These tensions cannot ultimately be resolved. The donation process should therefore be made as transparent as possible, so as to reduce vulnerabilities and conflicts of interest to a minimum. At the same time, it should also be borne in mind that donation of an organ can have positive effects not only for the recipient but also for the donor (e.g. partner no longer requires dialysis, etc.). In the case of non-directed (altruistic)[3] living donation, there is no direct relationship between donor and recipient. For both constellations, however – directed[4] and non-directed donation – the depth of the assessment is identical.

2.2. Tensions between beneficence and avoidance of harm

Living donation requires an intervention in a "healthy" individual in order to save or improve the life of a "sick" patient (recipient). From a medical-ethical perspective, this is an intrinsically paradoxical situation, creating unique ethical tensions, since it involves physicians putting at risk the life of the healthy donor in order to save or improve the recipient's life. Intuitively, this procedure runs counter not only to the principle of beneficence (vis-à-vis the healthy donor), but also to that of non-maleficence (vis-à-vis the healthy donor). These tensions can be resolved if one takes into consideration the fact that the donor is making a voluntary decision to do a good deed with potential benefits for both parties.

2.3. Ensuring the autonomy of the decision to donate

In the assessment of potential donors, all the health professionals concerned are required to ensure that ethical priority is always accorded to the autonomy of the decision to donate. They are to take account, primarily, of the desire to donate, but also always of the need to protect the donor. In practice, this means that they should focus not only on the voluntariness of the donation, informed consent to the donation process and the exclusion of hidden pressures and/or conflicts of interest on the part of the donor, but also on the health of the potential donor. In the protection of donors, consideration is to be given not only to medical aspects but also to psychosocial factors. If the risks for the donor are too great, donation must be refused. For the professionals involved, the tensions between respecting the donor's autonomous wishes and protecting the donor against risks may be ethically challenging.

2.4. Equity and fairness

With directed living donation – in contrast to the allocation of organs to patients on a waiting list – the principles of equity and fairness are not the focus of attention. However, not everyone has the same chance of receiving a living-donor organ transplant. According to a nationwide study, older patients without higher education were less likely to receive a directed living-donor transplant; this was also the case for patients not fully integrated into the labour market and especially for patients not living in a committed relationship.[5] Considerations of equity are thus also relevant here.

Donors should be aware that the costs of preliminary assessments, organ removal and aftercare will be borne by the recipient's health insurer. From a medical-ethical perspective, it is crucial that living donors should not suffer any disadvantages as a result of organ donation (e.g. when purchasing insurance, cf. Section 13.2). Donors are to be informed about possible difficulties.

In the allocation of organs from non-directed living donation, the principles of equity and fairness play an important role. Organs from altruistic living donors are allocated – like those from non-directed deceased donation – to the highest priority waiting-list patients, in accordance with the legally defined allocation criteria.

The allocation criteria are specified in detail in the Organ Allocation Ordinances of the Federal Council[6] and the Federal Department of Home Affairs (FDHA).[7] Based on the requirements of medical urgency and medical benefit, the aim is to make allocation as equitable and fair as possible.

3. Legal framework

The Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act) is based on Art. 119*a* para. 1 and 2 of the Federal Constitution. The principles for the removal of organs from living persons are set out in Art. 12 ff. of the Transplantation Act. These principles are more fully elaborated in the Ordinance on the Transplantation of Human Organs, Tissues and Cells (Transplantation Ordinance).[8] In connection with preliminary genetic assessments (cf. Section 7.4), the requirements of the Human Genetic Testing Act are to be complied with, and in particular the provisions concerning informed consent and genetic counselling.[9]

3.1. Prerequisites for removal (Art. 12 Transplantation Act)

Organs, tissues and cells may be removed from a living person if:

- the person has mental capacity and has reached the age of majority (i.e. 18 years of age);
- they have been comprehensively informed and have freely given their consent in writing;
- there is no serious risk to their life or health;
- the recipient cannot be treated with any other therapeutic method offering comparable benefits (cf. Section 3.2).

Organs must not be removed for purposes of transplantation from persons lacking capacity or from minors.

3.2. Subsidiarity

Subsidiarity means that living donation is only to be considered if treatment is not possible with other therapeutic methods offering comparable benefits (Art. 12 Transplantation Act). For patients with advanced kidney disease, renal transplantation is the most effective treatment method. Alternative treatment options such as haemodialysis or peritoneal dialysis, also known as kidney replacement therapy, are – compared with transplantation – associated with a lower quality of life and generally shorter survival. For this reason, pre-emptive (i.e. early) transplantation, avoiding dialysis, is advisable. The earlier the organ is transplanted, the greater the chances of successful transplantation. In addition, with living donation, prolonged, stressful waiting times can be avoided. Transplantation becomes a "plannable" event, the donor and recipient can be operated on under the best possible conditions, and there is less damage to transplants.

In the case of irreversible liver disease – unlike for kidney disease – there is no therapy whereby liver function can be replaced in the short or medium term. In this situation, intensive medical care serves merely to provide support for other affected organs and to reduce as far as possible the consequences of hepatic insufficiency. In acute irreversible liver failure or in chronic end-stage liver disease, liver transplantation is the only treatment option available.

3.3. Non-commercialism and prohibition of trade

Under Art. 6 Transplantation Act, it is prohibited to offer, grant, request or accept a financial gain or comparable advantage for the donation of human organs (cf. also Art. 119*a* para. 3 Federal Constitution). If there is a reasonable suspicion that donation is not being undertaken on a non-commercial basis, then the centre's legal department is to be consulted. It will provide support for the initiation of further steps (release from professional secrecy, charges brought under Art. 69 ff. Transplantation Act). Compensation for loss of earnings and reimbursement of expenses (cf. Section 13) for follow-up examinations and treatment associated with organ donation do not fall under the prohibition on financial gain.

Under Art. 7 para. 1 Transplantation Act, it is prohibited to trade in human organs. The same applies to the removal or transplantation of organs for which a financial gain or comparable advantage has been granted (cf. also Art. 119*a* para. 3 Federal Constitution). Under the Council of Europe Organ Trafficking Convention[10] Switzerland is also required to penalise organ trafficking offences committed abroad. Having ratified this Convention, Switzerland has included the relevant offences, and criminal liability for offences committed abroad, in Art. 69 para. 1 and 4 Transplantation Act. Also to be complied with are the relevant international guidelines.[11]

4. General aspects

4.1. Cross-over living donation

The option of cross-over living donation may be considered in the event of immunological incompatibility between donor and recipient. Cross-overdonation involves the cross-exchange of kidneys between two or more pairs. This option is regulated by the Cross-Over Living Donation Ordinance.[12] The details of incompatible pairs wishing to participate in the national programme are reported by transplant centres to the national allocation body, which periodically determines the best combinations for cross-over living donation among pairs. Only combinations in which both members of a donor-recipient pair are involved may be considered. Decisions on eligibility for or exclusion from the Cross-Over Living Donation programme are made in the form of a ruling (Art. 4 Cross-Over Living Donation Ordinance), which may be challenged via an appeal.[13] A rejection or exclusion must be communicated in writing, with reasons being stated.

There is, however, a certain risk that once a potential donor has actually been contacted, they may be unable or unwilling to donate. Thus, the fact that a kidney chain can be identified algorithmically does not automatically mean that it can actually be realised. This may not be possible, for example, for reasons of health, or if a donor-recipient pair does not accept a kidney chain donor, or if an organ cannot be transplanted.[14] When pairs are included in the Swiss Cross-Over Living Donation programme, they must be informed about this risk.

4.2. Age

Legally, living donation is possible from the age of 18.Many aspects of the lives of young adults, however, have yet to be determined (e.g. education, partnership, completion of family planning). Offers of living donation from very young adults are therefore to be evaluated with great caution. Living donation should remain a well-justified exception and should not adversely affect future life planning.[15] It is important to pay particular attention to the young (potential) donor's relationship with the recipient and to ensure that he or she is aware of alternative treatment options for the recipient (if available).[16]

There is no upper age limit for organ donation. However, the likelihood that donation will not be possible for medical reasons increases with age. In the information on donation, reference must be made to the higher risks of complications for older donors and to the risks associated with the surgical procedure. It should, however, additionally be mentioned that transplant function rates are also favourable with elderly donors (e.g. grandparents donating instead of parents to grandchildren).[17]

4.3. Sex

As regards living donation, there is still a marked discrepancy in the sex distribution of donors and recipients, which is not attributable solely to medical factors. According to the Swiss Organ Living-Donor Health Registry (SOL-DHR[18]), two thirds of kidney donors are women and two thirds of the recipients are men. These figures roughly correspond to the international average. Support should be provided for both women and men when they are considering donation. Any obstacles that could influence willingness to donate should be addressed at an early stage and possible solutions identified.

5. Information for donors and informed consent

Potential donors must receive oral and written information in lay-friendly language. If any barriers to communication exist, it must be ensured that the donor can understand the content of the information provided (e.g. using "simple language", decision aids, professional interpreting services). The most important elements of the information to be provided are listed in Art. 9 Transplantation Ordinance.

5.1. General information

- Purpose of and process for preliminary assessments, and for the removal and transplantation procedures;
- voluntariness (cf. Section 2.3 and Section 6) and the right to withdraw consent to donation at any time without giving reasons;
- non-commercialism of donation and the fact that commercial donation is a criminal offence;
- benefits and risks, especially also short- and long-term risks for physical and mental health, in particular: pain; hypertension and proteinuria; fatigue; need for organ replacement therapy (e.g. dialysis, transplantation); mortality; mental health problems (e.g. anxiety, depressive mood);
- possible effects on a pregnancy;
- the possibility that disease risks or diseases could be discovered as a result of medical assessments;

– possible consequences of a height and weight difference for the recipient;
– expected benefits and potential risks, and any other treatment options for the recipient;
– total period and time required for donor assessment, including time for reflection on the decision;
– expected duration of hospital stay and extent of unfitness for work, as well as other limitations;
– insurance, especially potential difficulties in purchasing supplementary insurance following living donation;
– reimbursement of expenses, especially compensation for loss of earnings, specifically the costs borne by the recipient's health insurer;
– special considerations for donations from abroad;
– basic data processing aspects; recommendation for lifelong, regular medical follow-up and the tasks of the living donation aftercare agency (SOL-DHR);
– availability of pre- and post-donation psychological care.

5.2. Additional information relevant for individual donors

As well as receiving general information, donors must be informed about aspects relevant for them personally. This may include the following information (depending on whether kidney or liver donation is involved):

– existing co-morbidity which could have adverse effects on the remaining kidney, especially diabetes, obesity, hypertension and/or genetic predisposition to nephropathy;
– if indicated, the importance of consistent use of medicines (e.g. antihypertensives);
– transplant immunology investigations such as tissue typing and HLA antibody testing;
– medical assessment, including: operability (perioperative risk); pre- and post-donation renal function; projection of long-term residual renal function, giving due consideration to age and adequate renal function with advanced age; possible contraindications to organ donation, such as malignant or infectious disease, comorbidities or psychosocial burdens; pre-existing pain;
– benefits and risks for the recipient, in particular: possible complications of transplantation, transplanted organ survival rate and recipient's chances of survival; possibility of transplanted organ loss; risk of recurrence of the underlying condition; advantages and disadvantages of dialysis; risk of the presence of anatomical variants (regarding blood vessels/bile ducts), as a result of which it may be "technically impossible" to divide the liver as required for removal.

The living donation assessment process may provide an opportunity to engage in reflection on the potential donor's health and lifestyle.

The donor should also be informed, in a situation-specific manner, about the possibilities of blood type-incompatible and cross-over living donation, specifically the Swiss Cross-Over Living Donation programme.

If genetic testing is performed as part of the preliminary assessments, information must be provided as specified in Art. 6 HGTA, in particular concerning the risks and physical and psychological burdens associated with the genetic test, and about the significance of test results for family members.

If the disease under investigation is not yet manifest, detailed genetic counselling must be provided before and after genetic testing (Art. 21 HGTA).

5.3. Additional aspects for donors from abroad

For living donors from abroad, the same rules apply as for organ donors from Switzerland. Certain aspects may, however, be more difficult to verify and/or will require additional attention.

5.3.1. Organisational aspects

– Is it assured that the potential donor can legally enter and leave the country?
– Can the entitlement to reimbursements for travel to Switzerland be established in good time (cf. Section 13.5)?
– How is it to be ensured that compensation can be provided for loss of earnings (cf. Section 13.5)?

5.3.2. Health system abroad

– What needs to be considered in general with regard to the health system in the country of origin, in particular: Can initial tests and assessments to identify or rule out obvious disqualifying factors for donation be carried out in the donor's home country? Can follow-ups be assured in the donor's country of origin?

5.3.3. Informed consent/cultural aspects

– Are there any language barriers necessitating the use of a professional interpreter?
– Is the declared relationship between potential donor and recipient convincing?
– Has the possibility of living donation by a person resident in Switzerland been explored in depth?
– Are there any culturally specific values and norms – associated for example with a conception of the roles to be played within a community – which could compromise the voluntariness of donation (e.g. family loyalty making donation "obligatory")?

If these questions cannot be adequately resolved, donation must be refused.

If a potential donor from abroad is accepted, the initial aftercare must be provided by the transplant centre.

In individual cases, the above-mentioned aspects may also be relevant for potential donors with a migratory background who are resident in Switzerland (e.g. language barriers, "voluntary" consent). Here, the checklist should also be helpful.

6. Psychosocial assessment

6.1. Goal

In the assessment, it must be determined whether the potential donor has capacity, their decision is based on adequate information, they have sufficient psychological and social stability, and their decision is voluntary. The assessment should cover the following points:

- capacity;
- motivation for organ donation, especially voluntariness and non-commercialism;
- absence of external pressure;
- psychosocial history, including pain history[19] and substance use history, as well as previous experience with surgical procedures and medical treatments;
- course of the decision-making process; existence of ambivalence;[20]
- previous management of psychosocial stress (including physical activity);
- current circumstances (social support network, occupation, finances);
- relationship with recipient, especially possible conflicts;
- donor's expectations regarding organ donation;
- knowledge of benefits and risks of donation for the donor;
- knowledge of benefits and risks of donation for the recipient;
- risk/benefit assessment showing preponderance of benefits;
- need for psychosocial support;
- right to seek a second opinion in the event of refusal.

The psychosocial assessment must be carried out by a medical specialist[21] or specialised psychologist[22] who is independent of the transplant team.[23] The assessment must focus on the individual (donor or recipient), but also consider the pair constellation. The potential donor is generally to be seen in person and alone. For the assessment, a number of interviews may be required. In certain cases, it may be appropriate, with the potential donor's consent, to seek the views of third parties (e.g. relatives, GP, treating physicians).

If the psychosocial assessment took place more than a year previously and donation has not yet occurred, it is advisable to carry out another psychosocial interview with the donor, so that any changes regarding the above-mentioned points can be identified.

6.2. Special donor situations

6.2.1. Donors donating to a minor

This constellation primarily involves close relatives donating to a child who is a minor. In these emotionally often highly stressful situations, as well as the individual assessment of the donor, a joint interview with the donor and recipient should generally also take place, so as to identify at an early stage specific familial stressors and/or possible problematic relationship dynamics which could, for example, have an adverse impact on the recipient's medical regimen adherence.[24] This joint interview should be conducted by the child psychiatrist/psychologist who has assessed the child. In the case of adolescents, it may also be conducted by the professional who has assessed the donor, but ideally jointly by the two assessors (i.e. child psychiatrist/psychologist and adult psychiatrist/psychologist).

6.2.2. Donors with a mental disorder

Mental disorders are not in themselves an exclusion criterion for donation. However, a mental disorder associated with significant impairment, especially unclear or restricted capacity (e.g. acute psychosis, severe depression or severe substance dependence) may be an exclusion criterion. This must be taken into account in the assessment. In addition, it must be carefully assessed whether refusal for psychosocial reasons would impose a greater burden than donation itself. In individual cases, the provision of psychological or psychiatric advice during the assessment process may be more appropriate than refusal of donation. If there are any doubts as to capacity, a psychiatrist is to be consulted who can provide an opinion on capacity following a personal assessment.

6.2.3. Donors with a person close to them opposed to donation

A potential donor may have a person close to them who is opposed to the prospective donation. For the donor, this may give rise to a conflict of loyalty vis-à-vis the recipient (e.g. a sister) and the close person (e.g. partner). To allow such situations to be identified at an early stage, key persons close to the donor should be involved in the psychosocial assessment.

6.2.4. Donors unwilling to donate

Whether someone wishes or does not wish to donate an organ is an individual, autonomous decision, which must be accepted by professionals without judgemental comments. Potential donors may experience a conflict between other people's expectations and their own fears and concerns in relation to donation. Sometimes unwillingness to donate or ambivalence is manifested in behaviour (e.g. failure to lose weight as required, delays, etc.). The transplant centre has a responsibility to inform the potential recipient that the potential donor is not currently an eligible candidate. Here, also, the potential donor is to be protected by the observance of professional secrecy.

6.2.5. Donors not accepted by the recipient

If a recipient cannot accept a donation, the person wishing to donate must be informed accordingly by the transplant centre. They will be told that they are not eligible as a donor in this constellation at the present time. Here, too, both the recipient refusing the organ and the potential donor are to be protected by professional secrecy. If so desired, psychological or psychiatric support can be provided for the recipient in communicating with the potential donor.

6.2.6. Donors particularly suitable for medical reasons

There may be situations in which, for medical reasons (e.g. HLA[25]-identical siblings), a donor is ideally suited for donation. This may become apparent, for example, when a family with a number of possible siblings is assessed. In this situation, the suitable donor may feel under increased pressure to donate. In subsequent interviews, this possible pressure must be taken into account and discussed with the potential donor.

6.3. Additional considerations for donations in the Cross-Over Living Donation programme

In the assessment of donors participating in the Swiss Cross-Over Living Donation programme, additional factors need to be considered. In the assessment interview, for example, it must be determined whether the donor has understood and accepted the distinctive psychosocial characteristics of living kidney donation within this programme (e.g. anonymity, organ allocation, lack of direct emotional benefits in the relationship with the recipient, or the risk of a so-called orphaned recipient[26]).

6.4. Additional considerations for non-directed donations

In the assessment of potential donors wishing to make a non-directed donation, additional factors need to be considered. In the assessment interview, for example, it must be determined whether the donor has understood and accepted the distinctive psychosocial characteristics of non-directed living kidney donation (e.g. anonymity, organ allocation, lack of direct emotional benefits in the relationship with the recipient).

6.5. Adherence in recipients

The reliability of the recipient in complying with a therapeutic regimen (i.e. adherence) is one of the most important requirements for the success of transplantation. Pre-transplant adherence is not necessarily indicative of post-transplant adherence. Problematic behaviours may influence post-transplant adherence. Such factors should be discussed with the donor-recipient pair.

7. Medical assessment

7.1. Risks

The risks for the donor are to be assessed using internationally valid criteria.[27] There are three types of risks:

– risks associated with living kidney or liver donation;
– risks associated with the health status of the potential donor (even without donation, possibly increased by donation);
– risks associated with genetic factors (even without donation, possibly increased by donation).

7.2. Risks following living kidney donation

7.2.1. Short-term risks

Mild perioperative complications (Clavien-Dindo I–II),[28] including genitourinary complications, occur in 10–20% of all living kidney donors. Severe complications (Clavien-Dindo ≥III), however, only occur in less than 3% of donors. The risk of perioperative mortality is less than 0.03%. SOL-DHR data show a higher rate of Clavien-Dindo III complications and more cases of urinary retention in donors over 70 years old, while more urinary infections are seen in donors over 60. Overweight, male sex and higher age are generally associated with an increased risk of complications. Higher age is usually associated with a longer convalescence. Like any other surgical procedure, nephrectomy involves a certain degree of risk (e.g. bleeding, wound healing disturbances, anaesthesia-related complications). Late or persistent complications (e.g. incisional hernias or positioning-related injuries) are, however, rare.[29]

7.2.2. Long-term risks

In long-term follow-up studies,[30] the vast majority of living kidney donors (93%) express a positive view and do not regret donation. In the SOL-DHR, living kidney donors report that their health remains good to excellent even years after donation.

Cardiovascular risk

Compared to non-donors with a similar health profile, living kidney donors have an increased risk of developing hypertension that requires treatment (20% higher incidence). An increase in blood pressure of 5 mmHg is expected to be seen five to ten years after donation. Hypertension following living kidney donation is associated with an increased risk of albuminuria.[31]

All donors should therefore be informed about the risks of hypertension. Advice should be offered so as to reduce lifestyle-related risks, and attention should be drawn to the importance of receiving prompt treatment for any post-donation hypertension. Monitoring is organised by the SOL-DHR, and donors should be encouraged to have these checks carried out.

Assessments of living kidney donation *in spite of* hypertension may vary, depending on the individual's age and duration of hypertension, existing cardiovascular risk factors, ethnicity or place of residence (e.g. a country where primary healthcare cannot be relied on and access to medicines following donation is uncertain). Well-controlled hypertension, with end-organ damage (especially albuminuria or hypertensive heart disease) either absent or controlled, does not in principle represent a contraindication to organ donation. All individual cardiovascular risk factors are to be taken into consideration in the risk assessment. If hypertension – with no end-organ damage – is first diagnosed in the course of the living-donor assessment, optimal antihypertensive control is required prior to a decision on eligibility for donation (e.g. 24-hour blood pressure monitoring three to six months after the start of treatment). At the same time, appropriate tests for end-organ damage must be performed (urinalysis to exclude albuminuria, ophthalmological examination, echocardiography). With albuminuria or end-organ damage affecting the eyes or heart, living donation is usually contraindicated. In special situations, end-organ damage may be considered acceptable.

Obesity and diabetes

While morbid obesity and diabetes are generally contraindications to donation, it should be assessed whether donation may be appropriate in individual cases where a person has an increased body mass index (>30 kg/m^2 but <40 kg/m^2) or metabolic disorders with an increased risk of diabetes (impaired fasting glucose/impaired glucose tolerance) or diabetes.[32] Such donors must be informed about the additional health risks, the development of diabetes, adverse impacts on the remaining kidney (development of proteinuria, accelerated kidney failure) and lastly the occurrence of cardiovascular events. A direct relationship between obesity and cardiovascular events following living kidney donation has not, however, been demonstrated to date.

In donor candidates who have undergone bariatric surgery, not only should an extensive evaluation of the overall risk be carried out, but also a specific assessment with regard to the occurrence of urolithiasis.

Other cardiovascular risk factors

There is evidence that donors who suffer from gout are more likely to develop acute or chronic kidney failure. For this reason, donor candidates with a history of gout episodes are to be informed about the increased risks and any measures which may be appropriate.

In patients, impaired kidney function and albuminuria are cardiovascular risk factors. However, since donors are not patients, it is not clear whether reduced kidney function following donation, or the occurrence of albuminuria in the absence of hypertension or diabetes, has the same significance – in the sense of a cardiovascular risk factor – as in patients with pre-existing conditions.

In summary, it can be said that the effects of living kidney donation in terms of the occurrence of cardiac events following donation have yet to be unequivocally established. In the first 10–15 years after donation, there is no major difference compared to non-donors. The development of left ventricular hypertrophy and a substantial decline in kidney function are, however, markers of an increased risk of potential cardiovascular events (KDIGO guideline[33]).

Advanced kidney failure after donation and need for kidney replacement therapy

Following living kidney donation, a long-term risk for the donor is the possible development of kidney failure.[34] According to the SOL-DHR, the risk of a need for kidney replacement therapy for living kidney donors who have donated in Switzerland is currently around 3/2500, usually arising at the age of over 80 years and after more than 20 years following living donation.[35]

Fatigue

Increased tiredness mainly occurs in the first 12 months after donation. According to SOL-DHR data, about 8% of donors develop tiredness going beyond normal postoperative fatigue.[36] After five years, 1.5% of the donors registered in the SOL-DHR still complain of fatigue. No correlation could be found with sex, age, glomerular filtration rate, hypertension or albuminuria.

Ethnicity

Depending on ethnicity, genetic and sociocultural determinants, a possible increase in the risk of metabolic or cardiovascular diseases should be taken into account. Potential ethnicity-related risks must be identified and discussed.

Substance use (including painkillers)

[37] Regular cannabis use may be associated with psychiatric comorbidities and cognitive impairments, as well as cardiovascular events and lung diseases. Clinically relevant renal complications may occur with synthetic cannabinoid use and with cannabinoid hyperemesis syndrome.

Persons with harmful substance use – especially intravenous use – are not suitable donor candidates on account of their dependence, withdrawal risks, infection risks and other increased risks for their own health.

With active tobacco use, there is not only an increased risk of cancer, cardiopulmonary disease and kidney failure, or progression of existing kidney failure, but also an increased risk of perioperative complications. Cessation of tobacco use prior to organ donation is therefore recommended. Potential donors must be made aware of these increased risks before donation.

Pregnancy

Pregnancy is possible after living kidney donation, but it is associated with an increased risk of pregnancy-related hypertension or pre-eclampsia.[38] In cases where family planning has yet to be completed, counselling is required prior to donation. Women explicitly wishing to have children should only be accepted as donors in exceptional cases. If pregnancy occurs after kidney donation, more intense monitoring is required.

Acceptance of donors with an increased risk profile

F or the decision whether donor candidates with an increased risk profile should be accepted, additional factors are relevant: age, overall risk, motivation for lifestyle changes, possibility of risks being exacerbated by genetic factors, and access to healthcare. The risk profile of the donor and recipient should be evaluated by the interdisciplinary team and judged to be acceptable.

7.3. Risks following living liver donation

7.3.1. Short-term risks

In contrast to living kidney donation, living liver donation requires substantially more complex surgery and is thus associated with a higher rate of postoperative complications. Among the most common complications are biliary leaks and superficial wound infections. In the literature, the complication rate varies fairly widely, but tends to be around 25–30%, with complications (apart from incisional hernias) usually arising within the first 30 days.[39] Donor mortality as a direct result of liver donation is 0.3%, although it may be subject to a degree of underreporting.[40]

Biliary complications

Among the most common postoperative complications are those concerning the biliary tract (up to 10%);[41] in particular, biliary leaks from the cut surface of the liver and, more rarely, infections (cholangitis) are observed. The usually relevant and persistent problems can be resolved by means of endoscopic retrograde cholangiopancreatography and stenting, or more rarely by percutaneous drainage.

Disorders of liver function

Much less common are transient disorders of liver function, corresponding to small-for-size syndrome, which may be accompanied by persistent hyperbilirubinaemia or ascites.

Vascular complications and bleeding

Intraoperative administration of blood products is rarely required in connection with donor hepatectomy (<10% of cases). Also very rare (<5%) is clinically relevant postoperative bleeding requiring transfusion or surgical intervention for haemostasis.[42]

Cardiopulmonary complications

Persistent pleural effusion may require placement of thoracic drainage, although this is usually only temporarily indicated. While other cardiopulmonary disorders such as pulmonary embolism, cardiac decompensation or pneumonia may occur, these tend to be rare events (<5% of cases).[43]

7.3.2. Long-term risks

In long-term follow-up studies, the vast majority of living liver donors (90%) express a positive view of donation and would be willing to donate again.[44]

Laboratory test abnormalities

Abnormal laboratory test results are observed, as is to be expected, after donation, with values generally returning to normal within three months. Transaminases, alkaline phosphatase, the international normalised ratio (INR) and albumin may still be slightly lower up to twelve months after donation, although these differences are probably not clinically relevant. The only laboratory parameter found to be consistently lower than before donation throughout a four-year follow-up were platelet counts.[45] In other studies, a correlation was demonstrated between a larger spleen size and lower platelet counts.[46] What this reduction in platelets means for the donor has yet to be elucidated.

Overweight and diabetes

Persons with prediabetes or moderate obesity may be accepted as donors if they are informed about the specific risks and receive nutritional advice. Post-donation aftercare should be provided on a regular basis and should include annual monitoring of metabolic parameters by a specialist.

Late surgical complications

Surgical complications which only arise at a later stage or persist for an extended period are incisional hernias or positioning-related injuries.[47] Incisional hernias may occur in 1–7% of donor operations, while positioning-related injuries – in some cases causing symptoms over a prolonged period – have been reported in 1–3% of cases.[48]

Chronic pain more than two months after donation

Altogether, 31% of donors still reported pain after six months, and 27% after twelve months.[49] Pain was generally mild, and interference with activities due to pain was limited. Risk factors for the presence or persistence of pain were female sex and a younger age. However, 4–13% of donors reported moderate to severe pain (≥4 on a 0–10 visual analogue scale) at some time during follow-up (up to two years after donation). After two years, 8% still reported moderate to severe pain.[50]

Fatigue

Clinically significant fatigue (>5 points above the normative mean PROMIS T-score) was reported by 15%, 9%, 8% and 4% of donors at 3, 6, 12 and 14 months respectively.[51] The risk factors identified for greater fatigue were female sex, having a spouse or long-term partner, a longer hospital stay, death of the recipient, pre-donation fatigue, a history of family disapproval of donation, and anticipation that life would be more worthwhile after donation.

Digestion problems

Digestion problems may occur after living liver donation. According to SOL-DHR data, such problems (e.g. cramps, flatulence, diarrhoea) were reported by 10 of 55 living liver donors (18.2%) when certain items were consumed (e.g. fruits, high-fibre food). They may persist even years after donation.

Psychosocial effects

Some donors suffer from marked reductions in quality of life for months or years after donation. One of the largest prospective multi-centre studies of psychological outcomes in living liver donors is that of Butt et al.[52] In this study, 271 (91%) of 297 donors were interviewed, using validated instruments, at least once before donation and at 3, 6, 12 and 24 months after donation. In the first two years after donation, low rates of major depressive (0–3%), alcohol abuse (2–5%) and anxiety syndromes (2–3%) were reported at any given assessment. Between 5% and 10% of donors reported impaired mental well-being at various time points.[53]

Significant predictors of mental well-being identified in the study were: age, gender, relationship to recipient, ambivalence and motivation regarding donation, and feeling that donation will make life more worthwhile. The study highlights the need for close psychosocial monitoring for those donors whose recipients died (n=27), since they may experience feelings of guilt as a result.[54]

7.4. Genetic aspects

Long-term outcomes of living donation can be influenced by genetic factors.[55] Recipients may suffer from a hereditary kidney disease, and a living donor who is a blood relative may be an asymptomatic carrier. If a recipient has polycystic kidney disease, such disease must be excluded in a blood-related living donor. In adults, this can be done by means of kidney imaging; genetic testing is not generally required. For other kidney diseases with a genetic predisposition or cause (e.g. specific tubulopathies or glomerulopathies, tendency to develop kidney stones, forms of thrombotic microangiopathy), genetic screening should be considered for a blood relative willing to donate. The development of renal function after nephrectomy can also be influenced by the donor's carrier status. Genetic screening can improve donor safety and can enable donation in cases where a blood-related donor is not affected. However, systematic genetic screening for hereditary kidney diseases in blood-related donors is not currently recommended. If a potential recipient is known to have a genetic mutation, specific investigations may be appropriate. If genetic testing is considered, the potential donor is to be informed in advance. In cases of presymptomatic genetic testing, in-depth genetic counselling is additionally required (cf. Section 5.2). For genetic testing, agreement to cover the costs is to be obtained in advance from the potential donor's health insurer, as the costs will not be reimbursed by the recipient's insurer.

8. Final assessment of donor suitability

The final decision on donation should involve a structured process, with discussions by an interdisciplinary board and adequate documentation of the results. Account should be taken of the assessments made by the various disciplines – including psychiatry or psychosomatic medicine, nephrology or hepatology, transplant surgery, cardiology and anaesthesiology. Particularly relevant are the immunological assessments of the potential donor and recipient by the transplant immunology group. The transplant coordination organisation should be involved. It may also be appropriate to obtain ethical support; at some centres, this is part of the standard procedure.

The decision on suitability will be based on the results of the psychosocial assessment, the medical diagnoses, the results of laboratory tests and imaging studies, and the surgical and anaesthesiological assessment. The decision will also take into account any attitudes expressed by the donor which could influence the outcome [e.g. rejection of resuscitation or blood transfusions (cf. Section 7.2.2)]. If, for example, the risks to the donor's life and health are too great, donation will be refused – even against the donor's wishes (cf. Section 2.3). All potential living donors should be assessed using the same criteria, which are based on international practice. Of particular relevance are the KDIGO guideline for kidney donation and the OPTN policy and BTS guidelines for liver donation.[56]

Both the donor and the recipient are to be informed of the final decision, verbally and in writing. Reasons must be given for a refusal (cf. Section 4.1). In situations where a refusal is not accepted by the donor and/or recipient, it should be recommended that a second opinion be sought at another transplant centre.

9. Pre-and post-donation support for the donor

Donors should receive support during both the suitability assessment and the organ removal process. This support should enable the donor, within a trusting relationship, to express any anxieties, doubts or concerns and to obtain answers.

Responsibility for providing support should lie with a clearly designated member of the transplant team. Following the donation, in addition to postoperative treatment and registry aftercare (cf. Section 10), consideration should be given to the possibility of the donor being contacted by the trusted person within the transplant team (e.g. the designated transplant coordinator/Advanced Practice Nurse) at defined time points, such as 3, 6 and/or 12 months after donation. Thereafter, it should be possible for further support to be provided, if necessary (e.g. in the event of transplant failure or death of the recipient).

Support is also to be provided following a negative assessment of donor suitability. This should ensure that both the donor and the recipient can fully understand the decision, and also that the refusal has been accepted without any new psychosocial disadvantages arising for the rejected donor.

10. Donor aftercare provided by the living donation aftercare agency

Under Swiss law, all persons who have donated a kidney or part of their liver in Switzerland are entitled to receive lifelong medical aftercare (Art. 15*a* Transplantation Act). The follow-ups are designed to ensure regular monitoring of living donors' health and appropriate intervention if health data deviate from the norm or if problems arise. Living donor aftercare is assured by the living donation aftercare agency (SOL-DHR). It is provided at defined intervals: first 1, 3, 5, 7 and 10 years after donation, and then every 2 years for the rest of the living kidney or liver donor's life. Donors who are resident abroad are also invited to attend for follow-up examinations. The legally prescribed follow-ups are financed by flat-rate payments made by organ recipients' health insurers or by the recipients themselves, if they do not have health insurance in Switzerland.

Living donors are invited to give their written consent to registration in the Swiss Organ Living-Donor Health Registry (SOL-DHR). Consent is obtained by the transplant centres and forwarded to the SOL-DHR. The donor will then be included in the registry.

Donors who do not wish to be registered in the SOL-DHR are informed by the transplant centre that they are personally responsible for health checks.

The goals of donor aftercare are as follows:[57]

- early detection of health problems arising after donation;
- informing the donor and the physician responsible in the event of any abnormalities, and providing individual advice or recommendations on treatment options;
- monitoring donor health in the short, medium and long term;

– description and quantification of early complications, providing basic information used in advising potential donors;
– health-related findings from long-term follow-up studies are also included in the information provided for potential donors;
– analysis of long-term medical and psychosocial data so as to improve the living donation process.

Findings from the analysis of study results for quality control purposes are to be made available to all transplant centres in an anonymised form.

11. Data protection and anonymity

Health data is sensitive personal data, which may not be passed on to the potential recipient or other third parties without the consent of the potential donor. The same applies, conversely, to the potential recipient's health data.

All donors must consent to the transmission of their health-data to the SOL-DHR; otherwise, they cannot be included in the registry. In the case of non-directed donation, the donor's information must – to permit allocation – be transmitted to the Swiss Organ Allocation System (SOAS) (Art. 22 para. 2 Transplantation Act); here, the donor's consent is not required. Participation in the Cross-Over Living Donation programme, and thus also transmission of data to the SOAS, does, however, require the written consent of the persons concerned (Art. 3 para. 1 let. c Cross-Over Living Donation Ordinance).

Donors making a non-directed donation and donors participating in the Cross-Over Living Donation programme remain anonymous until transplantation has taken place (Art. 18 Cross-Over Living Donation Ordinance), as the recipient should not know who is providing the organ. The aim is thus to prevent unnecessary burdens and make a possible withdrawal less likely. The teams involved, including the hospital accounts department, must be appropriately informed in advance so that they can ensure anonymity; for example, the name of the donor must not be visible on copies of invoices intended for the recipient.[58]

Anonymity may be lifted after the transplantation, if all the donors and recipients concerned so desire.

12. Compliance with national and international standards

It must be ensured that the ethical guidelines of the Declaration of Istanbul,[59] the WHO[60] and the Council of Europe,[61] as well as the requirements of the Transplantation Act and the implementing ordinances, are understood and complied with. Living donation decisions must be comprehensible, as far as possible, and organ trafficking, transplant tourism or pressure on the donor must be excluded.

13. Reimbursement of expenses and insurance

13.1. Costs of medical treatment, follow-up examinations and care

Under Art. 14 para. 2 Transplantation Act, the costs of transplantation (surgical procedure, other treatments and hospital stay) and the pre-donation assessment costs are to be reimbursed by the recipient's compulsory insurance in accordance with the Health Insurance Benefits Ordinance.[62] The costs of follow-up care directly related to donation (e.g. incisional hernias which may occur even years after donation) are to be reimbursed by the recipient's insurer (Art. 14 para. 2 Transplantation Act). Costs not arising from living donation are to be charged to the living donor's insurer. For donors registered in the SOL-DHR, the costs of lifelong follow-up will be reimbursed by the living donation aftercare fund, into which organ recipients' insurers – or the recipients themselves, if they do not have health insurance in Switzerland – make a flat-rate payment after every donation. The living donation aftercare fund is managed by the Common Institution under the KVG. For donors registered in the SOL-DHR, invoices for follow-up examinations are always to be submitted to the SOL-DHR.

The flat-rate payment is to be made if the donor wishes to have aftercare provided by the SOL-DHR (Art. 12*a* para. 2 Transplantation Ordinance). Donors not wishing to be registered in the SOL-DHR must contact the recipient's health insurer directly. Here, they should be supported as far as possible by the treating physician or the transplant centre. They should, however, be made aware that the process is more complicated.

13.2. Insurance

Under Art. 11 Transplantation Ordinance, it must be ensured that, for a period of at least 12 months after organ removal, donors are covered by insurance against the risks of death or disability occurring as a result of the procedure. In the event of death, a payment of CHF 250,000 is to be made to surviving dependants; in the event of disability, an integrity allowance of no more than CHF 250,000. The transplant centre responsible may, on behalf of the hospital, guarantee the requisite sums by means of an insurance policy or in a fund.

Living donors are usually healthy and have a higher life expectancy than the general population. From a medical-ethical perspective, therefore, they should not be disadvantaged as a result of their donation when purchasing insurance policies (e.g. life insurance, supplementary health insurance).

13.3. Reimbursement of expenses and loss of earnings

Under Art. 14 Transplantation Act, the recipient's insurer must bear the costs of compensation for the loss of earnings incurred by the donor in connection with organ removal. This principle applies for employees, the self-employed and recipients of unemployment benefit, and it covers the loss of earnings incurred as a result of pre-donation assessments and donation-related unfitness for work.

Donors do not need to submit a claim for loss of earnings to their own daily allowance insurance provider, but can contact the recipient's insurer directly. In the calculation of loss of earnings, no waiting periods are applied.

"Regulations concerning reimbursement of expenses and compensation for loss of earnings in living donation" have been developed by insurers who are members of the Swiss Association for Common Tasks of Health Insurance Companies (SVK) as well as non-member insurers.[63]

For employees, the basis for the calculation of loss-of-earnings compensation is the salary paid before donation (including incidental costs to be paid by employers and employees). For employees paid on an hourly basis, appropriate compensation must be calculated for the period of lost earnings. For the self-employed, loss-of-earnings compensation is calculated on the basis of the pre-donation income earned according to the current tax return and the most recent definitive tax assessment; for unemployment benefit recipients, the daily allowances paid before donation are the decisive factor. It is important to bear in mind in this connection the fact that, on request, a maximum of one month's salary will be financed in advance and that, in the event of prolonged unfitness for work, payments on account may also exceptionally be made.

The recipient's insurer must, in addition, reimburse all documented costs incurred by the donor in connection with the donation. In particular, this refers to travel expenses for the donor suitability assessment and for organ removal, and the costs of paid assistance required at home and in the workplace and for the care of close persons looked after by the donor. Board and lodging and travel expenses for follow-up examinations are not covered by the recipient's insurer. Follow-ups for living donors resident abroad may also be carried out at the donor's place of residence.

13.4. Role of the transplant centre

As part of the pre-donation assessment, the transplant centre is to inform potential donors about the reimbursement of expenses and compensation for loss of earnings, and about the necessary formalities in this regard. In practice, problems sometimes arise concerning the reimbursement of costs. The transplant centre is to support donors in asserting their claims vis-à-vis insurers.

13.5. Living donors resident abroad

For living donors resident abroad, the same rules are essentially applicable as for organ donors from Switzerland – in particular, the assurance of lifelong aftercare. The transplant centre must ensure that the recipient or the recipient's insurer abroad pays in advance the contribution to the living donation aftercare fund (Art. 12*f* para. 1 Transplantation Ordinance). It must also be established what costs will be reimbursed by the recipient's health insurer if problems (e.g. incisional hernias) arise following living donation.

In the event of donation-related complications arising shortly after donation, the costs are to be borne by the recipient's Swiss insurer. The treatment of disorders not unequivocally attributable to donation, such as hypertension arising many years later, are to be borne by the donor's insurer. For donors coming from a country where they lack health insurance or have only limited coverage, the question how long-term aftercare will be assured is to be discussed prior to donation.

In the case of donors resident abroad, it must be clarified with the recipient's insurer – before travel is booked – to what extent travel expenses for the donor suitability assessment and for organ removal will be reimbursed. In particular, it should be discussed in detail how often the donor will have to travel to undergo the necessary examinations and what costs will be incurred. Whenever possible, initial assessments should be carried out in the donor's country of residence.[64] Not all insurers in Switzerland are prepared to make international bank transfers. In such cases, payments for travel costs should be transferred to the recipient for forwarding to the donor. For follow-ups, no travel expenses will be reimbursed.

13.6. Non-directed organ donation

The rules described in the previous sections are also applicable for non-directed organ donation. With this form of donation, the insurer responsible for loss-of-earnings com-pensation and for reimbursement of expenses can only be identified when transplantation has taken place. As a re-sult, it is possible that several months may elapse between the time when expenses are incurred and loss of earnings arises, and the payment of compensation by the recipient's insurer.

If the assessment indicates that organ removal or transplan-tation is not possible, the costs arising for the donor in con-nection with a donation which cannot be carried out are to be borne by the recipient's insurer or, if the insurer is not known, by the Confederation (Art. 14 para. 3 Transplanta-tion Act).

13.7. Cross-over living donation

The rules described in the previous sections are also applicable for cross-over living donation. The costs are to be borne by the insurer of the recipient who forms an incompatible pair with the donor.

III. Annex

Follow-up parameters for living donors

Kidney

Parameter/time	At hospital discharge after kidney donation	Year 0, 1, 3, 5, 7, 10; then every 2 years	Year 0, 1, 5, 10, 14, 20, 24, 30, 34, etc.
Problem-oriented medical and psychiatric history, medication		X	
Partial clinical status (blood pressure, weight, scar, etc.)		X	
Well-being, mental and physical (SF-8™)			X
Social status (questionnaire)			X
MFI-20® questionnaire (fatigue measurement)			X
Serum creatinine*	X	X	
Haemoglobin A1c test*		X	
Spot urine dipstick/ urine sediment**		X	
Spot urine albumin/creatinine ratio*		X	
Early complications and pain evaluation	X		

* In central laboratory

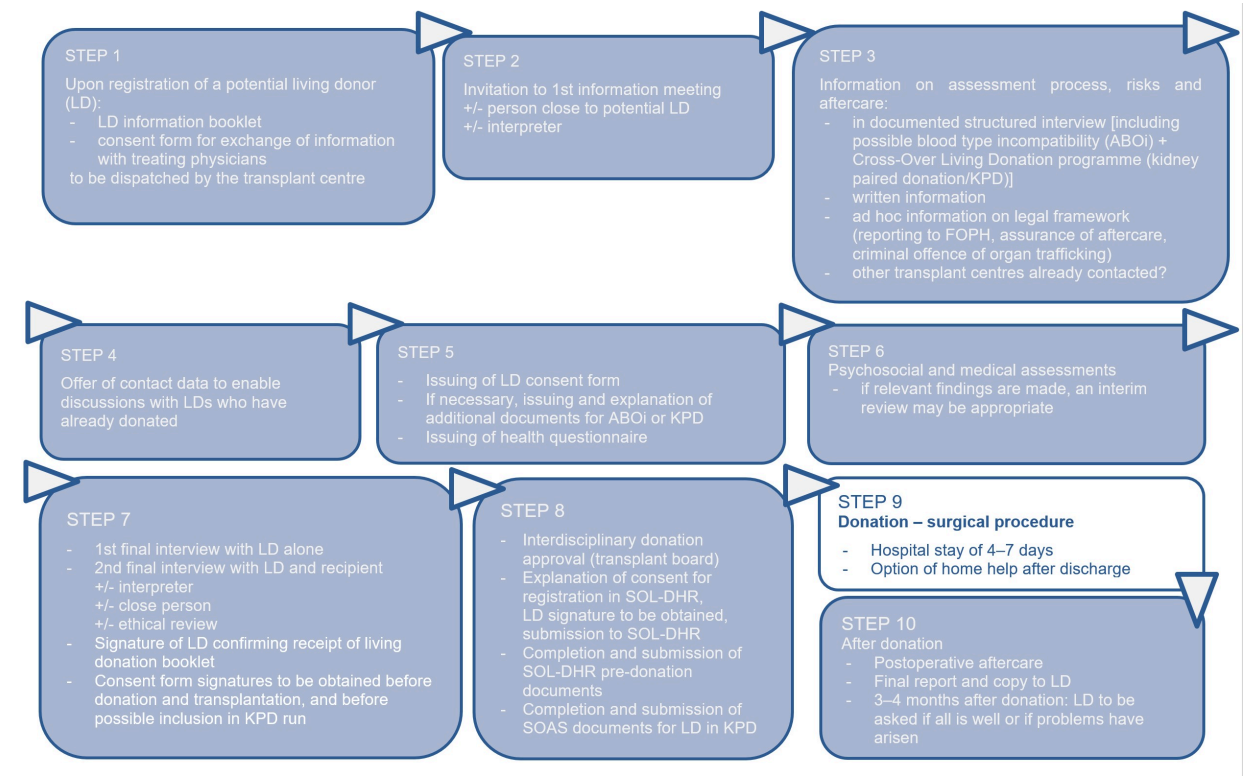
** Urine sediment examination only if urine dipstick test results are abnormal (after year 0 in the treating physician's laboratory)

Liver

Parameter/time	During liver donation	At hospital discharge after liver donation	Year 0, 1, 3, 5, 7, 10; then every 2 years	Year 0, 1, 5, 10, 14, 20, 24, etc.
Problem-oriented medical and psychiatric history, medication			X	
Partial clinical status (blood pressure, weight, scar, etc.)			X	
Well-being, mental and physical (SF-8™)				X
Social status (questionnaire)				X
MFI-20® questionnaire (fatigue measurement)				X
Liver function lab tests (blood)*		X	X	
Serum creatinine*		X	X	
Haemoglobin A1c test*			X	
Estimation of remnant liver weight	X			
Estimation of resected liver weight	X			
Early complications and pain evaluation		X		

* In central laboratory

Flowchart: Living kidney donation



Footnotes

[1] Cf. Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Transplantation Act, SR 810.21).

[2] Hereafter, "liver" is used as an umbrella term; strictly speaking, what is involved are liver lobes.

[3] Donation is described as "non-directed" or altruistic in cases where the donor does not wish to donate to a specific recipient and the donation goes to the person assigned the highest priority.

[4] Donation is described as "directed" in cases where the donor wishes to donate to a specific recipient.

[5] Cf. Achermann et al. 2021.

[6] Cf. Ordinance of 16 March 2007 on the Allocation of Organs for Transplantation (Organ Allocation Ordinance, SR 810.212.4).

[7] Cf. FDHA Ordinance of 2 May 2007 on the Allocation of Organs for Transplantation (Organ Allocation Ordinance, SR 810.212.41).

[8] Cf. Ordinance of 16 March 2007 on the Transplantation of Human Organs, Tissues and Cells (Transplantation Ordinance, SR 810.211).

[9] Cf. Federal Act of 15 June 2018 on Human Genetic Testing (HGTA, SR 810.12).

[10] Cf. Council of Europe Convention against Trafficking in Human Organs (SR 0.801.3, in force in Switzerland since 1 February 2021); Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors, Adopted by the Committee of Ministers on 14 June 2017 at the 1289th meeting of the Ministers' Deputies, rm.coe.int/1680726fb6

[11] Cf. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2018, www.declarationofistanbul.org; WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, 2010, www.who.int

[12] Cf. Ordinance of 18 October 2017 on the National Cross-Over Living Donation Programme (SR 810.212.3).

[13] Cf. Art. 68 Transplantation Act, under which such appeals are to be filed with the Federal Administrative Court.

[14] Cf. Ross et al. 2017.

[15] Cf. Grams et al. 2016.

[16] Cf. Thys et al. 2019.

[17] Cf. Bjerre et al. 2020.

[18] See www.sol-dhr.ch/de/

[19] Cf. Bruintjes et al. 2019, who report on chronic pain following donation, occurring more frequently in patients with pre-existing pain problems.

[20] Cf. DiMartini et al. 2012, who report that ambivalent donors are more likely to have negative feelings throughout the process (before and after donation).

[21] Specialist in psychiatry and psychotherapy, or physician training to become a specialist in psychiatry and psychotherapy under supervision.

[22] Federally recognised psychotherapist, federally recognised clinical psychologist, or psychologist training to become a psychotherapist or clinical psychologist under supervision.

[23] The assessment must be carried out by a professional with experience in assessments of this kind. It is recommended that the person concerned should have carried out at least four assessments (including reporting) under the supervision of an experienced professional.

[24] Cf. Dew et al. 2009.

[25] HLA = human leukocyte antigen.

[26] Rare case in which a recipient does not receive the allocated cross-over kidney. This may occur if, for example, the donor kidney has been severely damaged during removal or transport. The "orphaned recipient" thus remains on the waiting list, although their own partner has donated a kidney to the cross-over recipient.

[27] For living kidney donation: Lentine et al. 2017. For living liver donation: Organ Procurement and Transplantation Network (OPTN) Policies. Policy 14: Living Donation. 2022, www.unos.org/policy; British Transplantation Society (BTS) Guidelines. Living Donor Liver Transplantation. 2020, www.bts.org.uk

[28] The Clavien-Dindo classification is used to report and grade postoperative complications; Dindo et al. 2004.

[29] Cf. Burkhalter et al. 2017.

[30] See www.sol-dhr.ch/de/wissenschaftliche-aspekte/statistik/nieren

[31] Cf. Thiel et al. 2016.

[32] Cf. Soliman et al. 2022.

[33] Cf. Lentine et al. 2017.

[34] Cf. Ibrahim et al. 2009; Muzaale et al. 2014.

[35] See www.sol-dhr.ch/de/

[36] Little international data is available to date.

[37] Cf. Bugeja et al. 2021; Rein 2020; Ruckle et al. 2018.

[38] Cf. Matas and Rule 2022.

[39] Cf. Ghobrial et al. 2008; Cheah et al. 2013; as a rule, complications are mild and self-limiting (Clavien-Dindo I–II).

[40] Cf. Ringe and Strong 2008; Cheah et al. 2013.

[41] Cf. Benzing et al. 2018.

[42] Cf. Gorgen et al. 2018; severe vascular complications such as hepatic artery, portal vein or vena cava thrombosis are rare.

[43] Cf. Takagi et al. 2020.

[44] Cf. Dew et al. 2016; Butt et al. 2017.

[45] Cf. Trotter et al. 2011.

[46] Cf. Emond et al. 2015.

[47] Cf. Abecassis et al. 2012; Gorgen et al. 2018.

[48] Cf. Holtzman et al. 2014.

[49] Cf. Holtzman et al. 2014.

[50] Cf. Butt et al. 2018.

[51] Cf. Butt et al. 2018.

[52] Cf. Butt et al. 2017.

[53] Cf. Butt et al. 2017.

[54] Cf. Butt et al. 2017.

[55] Cf. Matas and Rule 2022.

[56] For living kidney donation: Lentine et al. 2017. For living liver donation: Organ Procurement and Transplanta-

tion Network (OPTN) Policies. Policy 14: Living Donation. 2022, www.unos.org/policy; British Transplantation Society (BTS) Guidelines. Living Donor Liver Transplantation. 2020, www.bts.org.uk

[57] Further information on living donation can be found on the websites of the Swiss Organ Living-Donor Health Registry www.sol-dhr.ch and the Swiss Association of Living Organ Donors www.lebendspende.ch.

[58] In the case of invoices issued in accordance with the Transplantation Act (loss of earnings, expenses), the recipient is not entitled to receive a copy, even if they know the donor.

[59] The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, 2018: www.declarationofistanbul.org

[60] WHO Resolution, WHA63.22 – Human organ and tissue transplantation, 21 May 2010: www.who.int/health-topics/transplantation

[61] Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors, Adopted by the Committee of Ministers on 14 June 2017 at the 1289th meeting of the Ministers' Deputies, www.coe.int; Convention against Trafficking in Human Organs(CETS No. 216), Council of Europe, Santiago de Compostela. 25 March 2015; available at www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216/

[62] Cf. FDHA Ordinance of 29 September 1995 on Compulsory Health Insurance Benefits, SR 832.112.31.

[63] See www.svk.org

[64] Cf. Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors, Adopted by the Committee of Ministers on 14 June 2017 at the 1289th meeting of the Ministers' Deputies, www.coe.int

Information on the preparation of these guidelines

Mandate

In March 2019, the Central Ethics Committee (CEC) of the SAMS appointed a subcommittee to revise the medical-ethical guidelines on living donation of solid organs (2008).

Subcommittee responsible

Professor Jürg Steiger, Basel, Transplantation Medicine (Chair)

Christine Bally, Bern, Nursing (until April 2022)

PD Dr Vanessa Banz, Bern, Visceral and Transplantation Surgery

Dr Isabelle Binet, St. Gallen, Nephrology/Transplantation Medicine

Dr Anne Dalle Ave, Lausanne, Ethics (until August 2021)

lic. phil. Irene Geiger, Basel, Psychology

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Emeritus Professor Paul Hoff, Zollikon, CEC Chair

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Dr Alex Frick, Basel, Psychosomatic Medicine

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Consultation procedure

On 24 November 2022, the Senate of the SAMS approved a draft version of these guidelines to be submitted for consultation to professional associations, organisations and other interested parties. The comments received have been taken into account in the final version.

Approval

The final version of these guidelines was approved by the Senate of the SAMS on 1 June 2023. Amendments in line with the partly revised Transplantation Act expected to come into force in 2025 may be incorporated without a fresh decision, provided that they do not involve substantial changes to the guidelines.

Original versions

English version in the original layout available at sams.ch/living-donation

German version available at samw.ch/lebendspende

French version available at assm.ch/don-organes-personnes-vivantes

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