

Organ transplantation: presumed or explicit consent?

SAMS factsheet

This factsheet brings together fundamental medical, legal and ethical considerations concerning organ transplantation. It is conceived as a contribution to the debate and as an aid to decision-making for the popular vote to be held on 15 May 2022 on the revised Transplantation Act.

1. Transplantation medicine

Organ transplantation is an evidence-based therapy for patients with irreversible organ failure. Transplantation medicine saves lives and offers sustained improvements in quality of life for organ recipients. In the absence of transplantation, patients with severe heart, lung or liver failure would die within a short time. In Switzerland, on average, 450 people per year receive one or more organs from a deceased donor.

Organ removal

Only very rarely is it the case that a person who wishes to donate their organs at the end of life is in fact, after death, in a situation where donation is medically appropriate. Individuals are only candidates for organ donation if they are unable to survive despite comprehensive treatment in intensive care or in cases where it becomes clear, after admission to the emergency department, that further treatment offers no likelihood of benefit.

Death of the entire human organism due to irreversible cessation of all functions of the brain occurs either as a result of primary brain damage or after permanent cardiac arrest. Following the determination of death, organs may be removed for transplantation provided that the other legal requirements are fulfilled. In certain cases, for the purpose of organ preservation prior to removal, the circulation is maintained by means of pharmacological and mechanical support and artificial ventilation.

If organs are to be transplanted, potential donors must first be identified. Physicians are required by law to raise the question of organ donation in cases where, given the medical condition of a dying or deceased patient, organ removal would be possible. This is done by the intensive care team providing treatment, in collaboration with specially trained professionals. No transplantation specialists are involved in the decision-making process; apart from being stipulated by law, this is also the case for organisational reasons.

As part of the assessment, it is ascertained whether the dying or deceased person has expressed any wishes concerning organ donation, e.g. via an entry in an organ donor register, advance directive or donor card. In addition, the attending physicians always consult the relatives. The aim is to determine and comply with the (presumed) wishes of the person concerned. It is thus ensured that the individual's autonomy is respected, and that in cases where persons wish to and can donate organs after death, their organs are in fact transplanted.

Organ implantation

Responsibility for organ implantation lies with a different interdisciplinary team – in particular, transplantation specialists. Their tasks include the medical assessment and care of organ recipients before, during and after transplantation. They are only deployed after consent to organ donation has been obtained. Organ allocation is carried out via a computer-based system in accordance with legally defined criteria. Organs from one deceased donor can save up to eight lives.

2. Legal foundations

Federal Constitution and Transplantation Act

In order to protect human dignity, privacy and health, organ transplantation is comprehensively regulated. The [Transplantation Act](#), Federal Act on the Transplantation of Organs, Tissues and Cells), which has been in force since 2007, provides the legal foundations for transplantation medicine in Switzerland. It is based on Article 119a of the Federal Constitution, which was accepted by a clear majority of voters and cantons in 1999.

The legislation includes strict requirements concerning the procedure for the determination of death in persons wishing to donate organs. As provided for in the Transplantation Ordinance, these are specified in detail in the SAMS Guidelines «[Determination of Death with Regard to Organ Transplantation and Preparations for Organ Removal](#)» issued in 2017. The legislation also states that organs are to be fairly allocated and prohibits payments for donations, as well as trade in human organs.

Popular vote on 15 May 2022

The popular initiative «Promote organ donation – save lives» was presented in March 2019. This calls for the introduction of a system of presumed consent instead of the existing explicit consent system, but without any regulation of the rights of relatives. For this reason, the initiative is opposed by the Federal Council and Parliament. They propose an extended presumed consent system, under which relatives are also to be consulted.

The Federal Council elaborated an indirect counterproposal in the form of a [revision of the Transplantation Act](#), which was submitted to Parliament following a broad consultation. The National Council and Council of States approved the revised Act and recommended rejection of the popular initiative.

The initiative committee subsequently decided on a conditional withdrawal of the popular initiative. «Conditional» means that the withdrawal will only become effective when the indirect counterproposal comes into effect, or if the people vote in favour of it in a referendum requested against it. As the request for a referendum against the revised Transplantation Act was successful, the people will vote on approval or rejection of the revised Act on 15 May 2022.

Core of the revised Transplantation Act: changeover from explicit to presumed consent

Under the current Act, organ removal is permissible if consent is available from the deceased person or if the next of kin consent, on request, to organ donation; their decision is to be guided by what they believe the deceased person would have wanted. This system is known as extended explicit consent. The lack of declared wishes on the part of the deceased is not taken to indicate either opposition or consent to donation. In this situation, the next of kin decide in accordance with the presumed wishes concerning organ donation. If there are no relatives, or if they cannot be contacted, organ removal is not permitted.

The revised Act provides for a changeover to extended presumed consent: anyone not wishing to donate their organs is required to document their opposition during their lifetime. The next of kin will continue to have the option of rejecting organ removal, taking the presumed wishes of the deceased into account.

In the future, in the absence of documented wishes, consent is to be presumed, unless organ removal is rejected by the next of kin in accordance with what they know or believe to have been the wishes of the deceased. If the person's wishes have not been documented and no relatives can be contacted, organ removal is not permitted.

At present, in situations where organ donation after death would be medically possible, the wishes of the deceased are not known in the majority of cases. The decision has to be made by the relatives. If they do not know the person's wishes, they usually reject donation. According to

surveys (including a representative survey conducted by DemoSCOPE on behalf of Swisstransplant¹ and the Swiss Health Survey 2017²), a majority of the Swiss population – between 50% and around 80% – wish to donate organs after death. Against this background, the current system appears to lead to a failure to respect such wishes in some cases. The changeover to extended presumed consent is designed to help ensure that, in cases where people wish to donate organs after death, their organs are in fact removed and donated. In addition, it is likely to be better known in future who does not wish to donate organs, so that deceased persons do not become donors against their wishes.

Establishment of a federal register: It is of the utmost importance that the wishes of the deceased for or against organ removal are known at the crucial moment. Under the revised Act, the federal authorities are required to establish a central register where such wishes can be recorded in accordance with data protection regulations. Everyone can record whether they are opposed to the donation of their organs after death or wish to donate organs (and if so which ones), and can modify their entry at any time. There is no legal obligation to record one's wishes.

3. Medical-ethical considerations

Of central importance from an ethical perspective are the need, firstly, to facilitate organ transplantation for the treatment of severely ill patients (fundamental principle of patient welfare/beneficence) and, secondly, to respect the wishes of potential deceased organ donors (fundamental principle of autonomy/self-determination). All the relevant processes are to be designed in such a way as to safeguard physical integrity both for donors and for recipients (fundamental principles of autonomy and non-maleficence).

Compliance with these ethical principles is possible both with the current extended explicit consent and with the proposed extended presumed consent system.

Fundamental considerations

- **Solidarity and distributive justice:** Transplantation medicine is based on the fundamental idea that people within a health system are willing and able to help one another. This principle of solidarity is of crucial importance for transplantation medicine. Also significant are questions of distributive justice: the organ allocation system must be transparent, equitable and fair.
- **Effective therapy:** From the viewpoint of medical ethics, transplantation medicine is essentially to be positively rated as a therapy which saves lives and offers sustained improvements in quality of life for organ recipients. To make this therapy available for severely ill patients, there is a public interest in the donation of organs.
- **Right to self-determination and respect for the patient's wishes:** Regardless of the system adopted – explicit or presumed consent – the primary goal is that decisions should reflect the wishes of the deceased. This works both ways: nobody should have an organ removed against their wishes and, equally, it must be ensured that those who wish to donate organs, thus making transplantation medicine possible, can do so. Of central importance is the careful evaluation and respectful implementation of (presumed) wishes.
- **Needs of relatives:** The deceased is never the only person to be affected by organ removal. Relatives, in an emotionally difficult situation, have to make a decision on organ donation, taking into account the presumed wishes of the deceased. This requires a

¹ Cf. Swisstransplant, Representative population survey. Results of the DemoSCOPE study, Bern, September 2015 (available in [German](#)). Information in [English](#).

² The results concerning organ donation from the Swiss Health Survey 2017, including statistical tables (raw data), are available [online](#) in French, German and Italian.

framework that enables treatment teams to create an atmosphere of trust and respect, and to accommodate relatives' needs.

- **Care and safety:** Physicians and other health professionals endeavour, with the utmost care, to safeguard donors' self-determination and physical integrity, and to provide close, empathetic support for relatives. With regard to organ donation, these professionals comply with numerous legal requirements, e.g. concerning the determination of death prior to organ removal or quality assurance for organs to be transplanted.
- **Preventing conflicts of interest:** The separation of the two treatment teams providing care for organ donors and recipients – required by law and by organisational considerations – ensures that conflicts of interest are avoided. Transplant surgeons are excluded from the process whereby a decision for or against donation is made in consultation with relatives and in accordance with the (presumed) wishes of the deceased

Considerations concerning extended explicit consent (the existing system)

- **Certainty, if wishes are known:** The aim of the explicit consent system is that people should actively and deliberately decide for or against organ donation. If a person has consented during their lifetime to organ donation, one can be quite certain that postmortem donation is in accordance with the wishes of the deceased.
- **Unknown wishes stressful for relatives:** Since very often a person's presumed wishes are not known, the decision in many cases has to be made by the next of kin, which they find stressful.
- **Relatives' decision not always in accordance with the wishes of the deceased:** If the relatives do not know whether the deceased would have consented to organ donation, they usually withhold consent. This decision is not necessarily in accordance with the wishes of the deceased, since surveys indicate that the great majority of the Swiss population would like to donate organs after death.

Considerations concerning extended presumed consent (the system proposed in the revised Act)

- **Appeal to individual responsibility:** The presumed consent system appeals to individual responsibility: all persons with capacity who are aged over 16 and resident in Switzerland are invited to actively express their wishes if they do not wish to donate organs. Individuals are thus called on to address the question of postmortem organ donation. To promote awareness of the right to self-determination, the provision of information for the public is vital: the federal authorities are legally required to provide detailed and comprehensible information about the option of recording in the register, and revoking at any time, one's opposition (or consent) to organ donation, and about the consequences of failure to record one's opposition.
- **No automatic donation in the absence of declared opposition:** Every person has a right to self-determination and physical integrity. If the revised Act is adopted and presumed consent introduced, intensive public information efforts will be undertaken. Even so, there will be some people who remain unaware that they are invited, during their lifetime, to declare their wishes if they are opposed to organ donation. What is crucial from an ethical perspective is that, in the absence of such a declaration, the relatives always have to be consulted, so as to ensure that no one becomes an organ donor against their wishes. Under the revised Act, if no declaration of the wishes of the deceased is available and no relatives can be contacted, organ removal is not permissible.
- **Greatest possible correspondence with presumed wishes:** At present, the great majority of people do not explicitly declare their wishes concerning organ donation, even though it is possible for them to do so. In future, with the presumed consent system, it will generally be assumed in such cases that a person does wish to donate, since – according

to surveys – the great majority support the principle of organ donation. By consulting the next of kin, the correctness of this assumption will, however, be checked in each individual case.

- **Measures to safeguard privacy:** The right to physical integrity is guaranteed by the Federal Constitution. This includes self-determination regarding the use of one's organs after death. There are concerns from an ethical perspective that these rights are essentially less well protected with presumed than with explicit consent. The safeguards specified in the revised Act – public information, straightforward exercise of the right to withhold consent via an entry in the central register, consultation of relatives, prohibition of organ removal in cases where relatives cannot be contacted – provide the best possible protection of privacy. Given the public interest in higher rates of organ donation, the Federal Supreme Court considers extended presumed consent to be proportionate and holds that this system does not violate fundamental rights (ruling BGE 123 I 112).
- **Possible effects on the availability of donor organs:** In several countries where presumed consent has been adopted to regulate organ donation, rates of donation are higher than in Switzerland.³ Switching to presumed consent offers a chance – though no guarantee – of an increase in the number of donations.
- **Establishment of a federal register:** The proposed establishment of a central federal register complying with data protection regulations may mean that more people record their wishes during their lifetime and these are then known at the crucial moment. Certainty as to the wishes of the deceased eases the burden on relatives and hospital staff. Rather than making an entry in the register, people may express their wishes or opposition in another legally valid form, e.g. in an advance directive, an organ donor card, or a discussion with relatives.

From a medical and ethical perspective, the regulation of organ donation should ensure that the wishes of as many people as possible – for or against donation – are known, so that, after death, action can be taken in accordance with the wishes of the deceased. It is up to voters to decide, on 15 May 2022, which system they prefer. The above considerations may serve as an aid to decision-making.

³ Federal Office of Public Health, Factsheet: Comparison of organ donation rates across Europe, February 2022 (available in [French](#) / [German](#) / [Italian](#)).

Glossary

Strict explicit consent: Organ removal is permissible only if consent has been given by the deceased during their lifetime and these wishes are known.

What does this mean in practice? Anyone wishing to donate organs must document their wishes. No action is required on the part of those who do not wish to donate organs. If no wishes have been expressed, no organs will be removed.

Extended explicit consent: Organ removal is permissible if consent has been given by the deceased during their lifetime. If no declaration of wishes is available, organ removal is still permissible if consent is given by the next of kin, who are required to take the presumed wishes of the deceased into account.

What does this mean in practice? People should document, and/or inform their relatives, whether or not they wish to donate organs. If a person has made no declaration (wishes unknown), their organs will generally not be removed if they die in intensive care, since relatives normally decide against organ donation if the wishes of the deceased are not known.

Strict presumed consent (not subject of the vote on May 15th): Organ removal is permissible if the deceased person has not declared their opposition during their lifetime.

What does this mean in practice? Anyone who does not wish to donate organs must document their opposition. No action is required on the part of those who do wish to donate organs. If a person has not expressed their opposition, organs will be removed after their death in intensive care, provided that the essential medical requirements are met. Consultation of relatives is not required.

Extended presumed consent (subject of the vote on May 15th): Organ removal is permissible if the deceased person has not declared their opposition during their lifetime and if the next of kin do not object. The relatives are required to take the presumed wishes of the deceased into account. If no relatives can be contacted, organ removal is not permitted.

What does this mean in practice? Anyone who does not wish to donate organs must document their opposition and/or inform their relatives. If a person has not declared their opposition, organs will be removed after their death in intensive care, provided that the essential medical requirements are met, as long as the lack of declared opposition is taken by the relatives to reflect the actual wishes of the deceased and they do not object to the organ donation.

Under the **declaration system**, everyone is called on to express and document their wishes for or against organ donation. However, since such a declaration cannot be demanded by the state, this approach has to be combined with an explicit (silence indicates refusal) or presumed consent system (silence indicates consent). The declaration could be documented, for example, in the electronic patient record.

Information on the preparation of the factsheet

This factsheet was prepared by a working group at the request of the [Central Ethics Committee \(CEC\)](#) of the SAMS and was approved by the CEC on 24.03.2022.

Members of the working group

PD Dr Vanessa Banz, Bern, Visceral and Transplant Surgery (Chair)
lic. theol., Dipl.-Biol. Sibylle Ackermann, SAMS (ex officio), Ethics
Dr Markus Eichelberger, Bern, Internal Medicine (CEC member)
Med. pract. Renato Lenherr, Zürich, Organ Donation Medicine
Dr Valerie Luyckx, Zürich, Nephrology/Ethics (CEC member)
Professor Pietro Majno-Hurst, Lugano, Surgery
Dr Mathias Nebiker, Aarau, Intensive Care Medicine
Professor Rouven Porz, Bern, Ethics
Professor Bernhard Rüttsche, Luzern, Law
Bianca Schaffert, MSN, Chair of SBK Ethics Committee, Nursing (CEC Vice Chair)
Dr Ewald Schorro, Fribourg, Nursing (CEC member)