

Position Paper Regarding Organ Donation

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1. Introduction

Organ transplants are the last resort in the treatment of a myriad of illnesses. Contemporarily, Switzerland faces a donor organ shortage. This leads to long waiting lists that cause the death of individuals, who are waiting for a donor organ.

2. Call to Action

The swimsa acknowledges ...

1. ... the benefits of organ donation in the treatment of seriously ill individuals.
2. ... the contemporary shortage of donor organs in Switzerland.

The swimsa endorses ...

1. ... general efforts of the federal government in the promotion of organ donation in Switzerland.
2. ... the development and implementation of specific, effective measures in the endeavor to combat the donor organ shortage in Switzerland.
3. ... the introduction of the opt-out solution according to the criteria elaborated on below.

The swimsa demands ...

1. ... an elaborate design of the opt-out solution, which accounts for the assumed will of the deceased person and consults their relatives.
2. ... that upon the implementation of the opt-out solution, sufficient information to the general public is provided and that professionals in healthcare receive additional corresponding education and training. In order to secure the latter, the swimsa demands the reformulation of article 53 of the Transplantation Law so that it encompasses additional training of healthcare professionals in organ donation.
3. ... the assay of additional instruments, which periodically suggest declarations regarding organ donation (e.g. according to the declaration-model introduced by the NEK).
4. ... increased provision of information to the general public regarding organ donation and related topics (e.g. brain death).
5. ... reinforced integration of the topics of organ donation and transplant medicine in medical studies.

3. Main Text

3.1 Starting Position

3.1.1 Purposes of Organ Transplants

The transplantation of an affected organ is often the last resort in the treatment of a myriad of illnesses and may bring the affected individual back quality of life, save their life, or at least prolong their life for a certain duration.

The World Health Organisation (WHO) describes the purposes of transplants as follows:

“Transplantation of human cells, tissues or organs saves many lives and restores essential functions where no alternatives of comparable effectiveness exist” (1)

3.1.2 Available Organs

The organs used for transplant come from a variety of sources.

Living organ donation is a possibility in case of paired organs like the kidneys. Additionally, a small number of segmental liver transplants are also performed in Switzerland. In other countries, parts of the lung and small intestine, and less frequently the pancreas, are transplanted from living donors. (2) The number of living donors in Switzerland was relatively consistent between 2014-2018. (3)

Due to the aforementioned restrictions, the majority of donors in Switzerland are currently deceased individuals who consented to organ donation during their lifetime or persons who are represented by their relatives in the event of ambiguity regarding their will. There was a slight increase in the number of said deceased organ donors between 2014-2018, with donations after prolonged circulatory arrest (Non-Heart-Beating-Donations, NHBD = Donations after Cardiocirculatory Death, DCD) showing a particularly strong increase in the last 2 years of the aforementioned period. (3) These have been performed again in Switzerland since 2011. (4) However, the vast majority of deceased donors still belong to the category of donations after death due to primary brain damage (Heart Beating Donations, HBD = Donations after Brain Death, DBD). (3)

For better comparability between different countries, donor numbers are standardized according to the number of inhabitants and presented as donors per one million inhabitants. In 2018, the figures were 18.6 donors per one million inhabitants for deceased donors and 14.1 donors per one million inhabitants for living donors. (3)

3.1.3 Shortage of Organs

Despite the aforementioned slight increase in donor numbers, there is still an organ shortage in Switzerland, i.e. the waiting lists for a required organ are long and donor organs cannot be found in time for all patients. At the end of 2018, there were a total of 1412 patients on the waiting list, around 60 people fewer than in the previous year. 68 people on the waiting list died in 2018 because donor organs could not be found in time - 7 fewer than in the previous year. The average waiting times for livers and kidneys decreased, while they increased for hearts and lungs. The longest wait was for kidneys (949 days on average), while the shortest wait was for livers (326 days). (3)

3.1.4 Legal Situation

The laws which govern procedures in the areas of organ donation and transplantation medicine are set out in the Federal Law on the Transplantation of Organs, Tissues, and Cells (Transplantation Law, TxG). The regulations on organ removal focus on the will of the deceased person. Primarily, organ removal is only permissible if the person consented to organ donation during their lifetime. (4) This can be done, for example, through a donation card or a living will, and it is now also possible to register in an online registry hosted by the national foundation Swisstransplant (5). This method is referred to as the consent solution.

In Switzerland, the so-called "extended consent solution" applies. This means that in the absence of documented consent, an attempt is made to ascertain the presumed will of the deceased person. This is done by questioning the relatives, who then decide on behalf of the deceased person. (4) It must be emphasized here that the presumed will of the deceased and not the intentions of the relatives are decisive. The TxG explicitly states that the relatives must take this into account in their decision and that it takes precedence over their own intentions. (4)

3.2 Current Efforts to Increase the Numbers of Donors

3.2.1 Action Plan "Mehr Organe"

In 2013, the Swiss government launched the action plan "Mehr Organe" with the aim to increase the number of deceased organ donors from 13.6 donors per one million inhabitants to 20 donors per one million inhabitants by 2018 (5). This was done with the backdrop of a joint study by the Federal Office of Public Health (FOPH), Swiss university hospitals, and Swisstransplant called "Swiss Monitoring of Potential Donors" (SwissPOD). This study estimated that the maximum donor potential in Switzerland was 36.3 donors per one million population (6), almost 3 times higher than the 13.7 donors per one million population at that time. (7)

The action plan intended to increase the number of donors through the adjustment of administrative measures and not due to alterations made to the TPG. Four fields of action were identified:

1. Education and training of medical professionals
2. Processes and quality management
3. Structures and resources in hospitals
4. Public campaigns and relations

The first three fields of action were delegated to Swistransplant and the Comité National du Don d'Organes (CNDO), while the implementation of the fourth field of action was conducted by the FOPH. (8)

Despite not reaching the numerical target set, the FOPH draws a positive balance, but refers in particular to the still high rejection rate of 60% in cases where the relatives have to decide in place of the deceased person. (8)

In May 2018, it was decided to continue the action plan from 2019 to 2021, with a new target of 22 donors per one million inhabitants by 2021. The fields of action remain the same. (5) Some adjustments were made to the individual measures. Among other things, there is to be an increased focus on the processes for DCD donors. In addition, the conditions under which discussions with relatives take place are to be analyzed and improved. (5) Regarding field of action 4, the goal is to reduce the refusal rate of relatives to below 40%. (9)

It is planned to transform the action plan into a permanent promotional program starting in 2022. (8)

3.2.2 Implementation of the Opt-Out Solution

As described above, the extended consent solution currently applies in Switzerland. In addition, there are other models for legally regulated organ donation. In particular, the so-called opt-out solution is widespread in many countries, including the majority of Europe. (10)

In contrast to the consent solution, the opt-out solution is not based on an opt-in system, but on an opt-out system. This means that for organ removal to be possible, explicit consent is not required, but rather the absence of a documented rejection is sufficient in principle. Since implicit consent is assumed here in the absence of this explicit rejection, this principle is also referred to as "presumed consent".

3.2.2.1 Types of Opt-Out Solutions

As with the consent solution, there are options for structuring the opt-out solution in different ways. Narrowly defined models accept only the explicit expression of the will of

the person in question (e.g. by entry in an objection register). Solutions with so-called "extension" also provide other possibilities, in particular a consultation of relatives analogous to the model of extended consent. (11) Additionally, an absolute right of the relatives to object could also be an option (see following section).

3.2.2.2 Opt-Out Solution in Regard to the Partial Revision of the TxG in 2015

In 2013, Felix Gutzwiller, a member of the Council of States, introduced a motion during the discussion of the Transplantation Law to include an opt-out solution with an additional right of objection for relatives in the TxG. Daniel Stolz made the same motion in 2015 during discussions held in the National Council. Both motions were rejected. In the final vote of both Councils, the version without the opt-out solution was adopted. (12)

3.2.2.3 Federal Public Initiative "Organspende fördern - Leben retten"

In October 2017, the collection period of a federal public initiative entitled "Organspende fördern - Leben retten" (organ donation initiative) of the Riviera section of the non-profit organization "Jeune Chambre International" (JCI) started. (13) By the end of the collection period in April 2019, the required 100,000 signatures were collected and the Federal Chancellery informs that the initiative has come into effect as of April 18, 2019. (14)

The initiative's phrasing allows for interpretational differences. The text reads as follows:

"Die Bundesverfassung wird wie folgt geändert:

Art. 119a Abs. 4

Die Spende von Organen, Geweben und Zellen einer verstorbenen Person zum Zweck der Transplantation beruht auf dem Grundsatz der vermuteten Zustimmung, es sei denn, die betreffende Person hat zu Lebzeiten ihre Ablehnung geäußert." (15)

Translation:

The Federal Constitution is changed as follows:

Art. 119a Abs. 4

The donation of organs, tissue, and cells of a deceased person for the purposes of transplantation rests on the grounds of assumed consent, except for cases in which the person in question said otherwise while they were alive.

The wording of the initiative leaves a great deal of room for interpretation; in principle, all the above-mentioned forms of the opt-out solution would be possible under it. If the initiative is accepted, the two chambers of the Swiss Federal Assembly would draft corresponding legislation at the federal level, presumably through a new revision of the TxG. In view of the negative stance taken in the partial revision in 2015 (see above), a rather broad implementation (in any case with consultation of relatives, possibly also with an explicit right to object) can be assumed despite the different composition of parliament.

3.2.2.4 Indirect Counterproposal of the Federal Council

On June 14, 2019, the Federal Council announced that it supported the concerns of the initiators of the organ donation initiative and to this end also welcomed the introduction of the contradiction solution. However, the Federal Council did not want a narrow form of the opt-out solution in which the relatives do not have to be involved. It favors a solution that provides for an extension in the sense of consulting the relatives regarding the presumed will of the deceased person. In order to ensure this, it would commission an indirect counterproposal from the Federal Department of Home Affairs that would contain these points. (16)

On September 1, 2019, the Federal Council commenced consultations regarding said indirect counterproposal. (17)

The defining article was phrased as follows:

Art. 8 Voraussetzungen der Entnahme

1. *Organe, Gewebe oder Zellen dürfen einer verstorbenen Person entnommen werden, wenn:*
 - a. *der Tod der Person festgestellt worden ist; und*
 - b. *die Person vor ihrem Tod der Entnahme nicht widersprochen hat.*
2. *Liegt weder ein Widerspruch noch eine andere Erklärung zur Spende vor, so können die nächsten Angehörigen der Entnahme widersprechen. Sie haben dabei den mutmasslichen Willen der verstorbenen Person zu beachten.* (18)

Translation:

Art. 8 Prerequisites of Removal

1. Organs, tissue, or cells may be removed from a deceased person if:

- a. death has been determined; and
 - b. the person did not refuse the removal before their death.
2. If neither a refusal of nor a consent to a donation is available, relatives of the deceased person may refuse the removal. They must adhere to the will of the deceased person in doing so.

In addition, restrictions are made in the following: If the next of kin cannot be reached within a reasonable period of time (this is to be determined by the Federal Council via ordinance), the organs may in principle be removed, with the exception of persons under 16 years of age, persons permanently incapacitated or incapacitated for a prolonged period of time, and persons residing abroad (the latter with certain exceptions, e.g. cross-border commuters). In the case of these groups of persons, consultation with the relatives is necessary. (18)

Consultations end on December 13, 2019. (17)

3.3 Additional Measures in the Field of Organ Donation

In the following, some further points are introduced that would have a positive impact on organ donation in Switzerland, irrespective of whether a system change to the opt-out solution is implemented, and to which great attention should be paid in any case. The consultation period ends on December 13, 2019. (17)

3.3.1 Declaration-Model (Proposal by the National Ethics Committee)

The declaration-model proposed by the National Ethics Committee (NEK) intends for individuals to receive information about organ donation each time they renew an ID card or, alternatively, every two years at their general practitioner's office, as well as the opportunity to directly register their will to do so. (19)

The swimsa supports any proposal to increase the number of informed declarations of will, as this would promote self-determination and provide greater clarity.

However, if the declaration-model were to replace the opt-out or consent solution, it would be mandatory for the will of every person resident in Switzerland to be known. Since this seems unrealistic, the swimsa sees the declaration-model rather as a supplement to one of the other two solutions.

3.3.2 Information of the General Population

As the NEK report makes clear, sufficient information is necessary for an autonomous decision. (19) Correct knowledge about organ donation and, in particular, knowledge about the need for organs are associated with more entries in organ donor registers and a positive attitude towards organ donation (20-22) . A lack of information also results in great uncertainty, which in turn can lead to concerns such as mistrust in the irreversibility of brain death or fear of organ trafficking. (23) It is therefore incredibly important that the population is informed about their rights regarding organ donation as well as being educated about related issues, such as brain death. This could be done, for example, as described in the declaration-model.

3.3.3 Information Amongst Medical Students

Organ donation is rarely discussed in medical studies. Educating medical students about organ shortage, brain death, the process of organ donation, etc. would contribute to better informedness overall. On the one hand, medical students could be actively encouraged to talk about the topic with their relatives and friends. On the other hand, it is very important - especially in regard to their future work - that they are able to provide correct information. A study conducted in Switzerland showed that the education of medical staff - especially about the processes of organ donation - correlates with the rate of consent (24). This should be considered positive in that consent is statistically more likely to be in accordance with the will of the deceased person (see above). In addition, intervention studies were conducted that showed that in just one lesson, medical students' knowledge of the topic can be significantly improved (25,26). It is important to raise awareness among medical students on the topic of organ donation and to ensure that they are properly informed on key issues. Like the Federal Representation of Medical Students in Germany (the bvmd) (27), the swimsa calls for a deeper integration of the topics of organ donation and brain death into medical studies.

3.3.4 Education and Training of Healthcare Professionals

The relevance of training healthcare professionals is obvious. The situation in which a close relative has died or is dying is already very stressful. Addressing the topic of organ donation in this situation requires a great deal of care and thus good training, especially in the area of communication.

Various studies demonstrate the important role of staff training, including in communication skills, both in relation to the experience of relatives and to the consent rate itself. (24, 28) The positive impression relatives have remains even when staff point

out incorrect views they have regarding organ donation.(28) Specific factors such as a calm conversational atmosphere also lead to an increased rate of consent. (29) On the other hand, a negative attitude of the person conducting the conversation toward organ donation and inferior informedness about organ donation increase the refusal rate. (30)

A higher approval rate should be weighted positively in that it is not due to conviction, but rather due to more information or a less stressed atmosphere. In addition, consent to organ donation reflects the patient's opinion in the majority of cases.

Especially after a system change from the consent to the opt-out solution, it is important to (re)train the health care staff so that correct information is passed on from all sides and the new system can be adequately explained and elaborated on.

For these reasons, the swimsa calls for sufficient, sustainable training of healthcare professionals, especially in regard to a system change.

3.4 Arguments and Positions on the Opt-Out Solution

3.4.1 Pro Arguments

3.4.1.1 Increase of the Number of Donors

Countries that have already introduced the opt-out solution have, on average, higher numbers of donors per million inhabitants than countries with the consent solution (11, 31). There is still insufficient evidence to prove a causal relationship. However, there is growing evidence that there is a relationship between higher donation rates and the opt-out solution (32).

3.4.1.2 Adherence to the Will of the Deceased Person

Various surveys of the Swiss population show that the vast majority (70-80%, depending on the survey) would be willing to donate their organs (33-35). Since the will of the deceased person is usually not known, the relatives decide in their place under the current consent solution - and usually against the donation of the organs (36). The introduction of the opt-out solution is intended to better represent the actual will of the deceased person. The relatives can assume that the deceased person wanted to donate their organs. This would be true in most cases even if there were not still a register in which one can enter one's name in case of being unwilling to donate one's organs.

3.4.1.3 Relief of the Relatives

In the current situation, if the deceased never expressed his or her will, the entire responsibility of deciding in the patient's best interests for or against organ donation lies

with the relatives. Under the objection solution, the relatives can in principle assume that it was the will of the deceased person to donate his organs. However, if they are convinced that this is not the patient's will after all, they can still refuse organ donation in the variants with extensions that are currently being discussed in Switzerland. On the one hand, therefore, the relatives are relieved of having to make a decision on their behalf in this difficult situation. The possibility to object provides additional security for those who do not wish to donate their organs (37).

3.4.1.4 Support in the General Population

Two studies carried out in recent months show independently of each other that the majority of the population is in favor of the opt-out solution. This is true even in the original form of the organ donation initiative, which, in contrast to the extended consent solution presented by the Federal Council, does not explicitly regulate the role of relatives and delegates the final formulation to parliament (33, 34). It therefore appears to be acceptable for the majority of the population to donate their own organs without having to have actively consented to this in every case.

3.4.1.5 Preservation of Values

The opt-out solution embodies a worldview characterized by altruism. It does not want to make it compulsory to pass on organs that are still functioning after death to people who urgently need them, but it does want to establish this as a norm that must be actively opposed. This was also one of the main arguments on the part of the proponents in the parliamentary debate on the partial revision of the Transplantation Act (12). The National Ethics Committee (NEK) describes this in its 2019 report on the contradiction solution as follows:

“Die Solidarität impliziert Vorstellungen von Gegenseitigkeit, Interdependenz, Fürsorge und Anteilnahme (Jennings & Dawson 2015) und hat bei der Widerspruchsregelung einen hohen Stellenwert. Bei diesem Modell wird gleichsam davon ausgegangen, dass die Betroffenen stillschweigend eingewilligt haben, im Sinne einer solidarischen Grundhaltung zum Gemeinwohl beizutragen. In diesem Sinne fördert die Widerspruchsregelung die Solidarität.” (36)

Translation:

Solidarity implies thoughts of reciprocity, interdependence, care, and empathy and is of a high value in the opt-out solution. In this model, it is assumed that the person in question tacitly agreed to contribute to a common good based on a solidaric disposition. As a result, the opt-out solution promotes solidarity.

It adds, however, that it is arbitrary whether the government may play a role in the definition of ‘solidarity.’ (36)

3.4.2 Contra Arguments

The removal of organs from a person who does not want to donate is perceived as a more severe intervention than the reverse case of not removing organs from a person who would actually have wanted to donate.

According to the NEK, Article 10 of the Federal Constitution of the Swiss Confederation (BV) guarantees a right to physical integrity, which may be affected in particular by preparatory medical measures or by errors in brain death diagnosis. In addition, a right for self-determination in matters of the body can be derived from Article 13 of the BV, which also extends beyond death. These rights are not absolute, however, but can be restricted under Article 36 of the BV if there is a public interest in doing so, as long as this restriction is proportionate (36). This makes it necessary to inform the population as profoundly as possible in the event of the introduction of the opt-out solution, but whether this is possible in every case is questionable. The extension with consultation of the relatives brings a certain additional security in cases in which no entry was made in the register, but a negative attitude towards organ donation was expressed to the relatives.

However, the Commission notes that, as with the extended consent solution, this involvement of the relatives imposes a responsibility on them that they do not have in the case of a narrow regulation. In addition, it is not guaranteed that the will of the deceased person would be respected in every case, e.g. because it would not be correctly expressed by the relatives. (36)

In various places (e.g. in the statement of the NEK from 2012), (38) it is stated that the opt-out solution, in order to circumvent the above-mentioned problems, would have to force people to make an active statement, i.e. through an obligation to make a statement. This in turn deprives people of the right not to have to decide at all.

3.4.3 The swimsa's Stance on the Opt-Out Solution

The swimsa recognizes that under the opt-out solution, ethically problematic situations may arise under certain circumstances, which may weigh heavily in individual cases.

However, the swimsa is of the opinion that the positive effects outweigh these concerns:

It is unacceptable that with such a high willingness to donate amongst the general population, as shown by the surveys, dozens of people die on the waiting list year after year. (33- 35) Although the evidence is insufficient to prove a causal relationship, there is growing evidence that there is a link between the opt-out solution and higher donor rates. For this reason, the opt-out solution appears to be a suitable means for the swimsa to increase donor numbers. Such an increase is urgently needed.

Additionally, the swimsa believes that under the opt-out solution the will of a larger number of people will be met when deciding on the removal of organs. The swimsa also believes that changes regarding the initial consultation of the relatives have the potential to relieve both the relatives and the healthcare professionals involved.

Furthermore, the swimsa is of the opinion that the change in values towards solidarity, which could occur in the long term as a result of the introduction of the opt-out solution, can be considered highly positive.

Lastly, the swimsa is in favor of the contradiction solution in particular because it has a great deal of support amongst the general population.

In conclusion the swimsa means to declare the following:

Swiss medical students are in favor of the opt-out solution when adhering to the following qualifications and criteria:

1. The decision whether or not to remove organs must adhere as closely as feasibly possible to the will of the deceased person.
2. In support of this, the possibility to register one's will regarding organ donation is afforded and maintained to every member of the population. Moreover, in case of the lack of a registered will, relatives of the deceased person are consulted. Said relatives must base their decision on the assumed will of the deceased person.
3. Detailed and accessible information that is factually correct in its content regarding organ donation and the entailed legal rights and regulations is provided to the population. The conceptualization and distribution of said information must be developed and planned to reach as many people as possible. The goal is to enable the population of Switzerland to engage with the concept of organ donation as early as possible.
4. Healthcare professionals are adequately educated and trained in regard to new regulations.

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