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Summative Evaluation of the Transplantation Act (1st stage)

**Abstract and Executive summary of the report for the attention
of the Federal Office of Public Health**

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Abstract

The Transplantation Act (TxG) has been in force since 1 July 2007. The Federal Office of Public Health (FOPH) has, in accordance with Art. 55 TxG, commissioned a summative evaluation in which the following subject areas will first be examined: informing the public, determination of death and preparatory medical measures (PMM), the allocation of organs and the quality of transplantations. This evaluation examined the extent to which the practical implementation is legally compliant and the legal objectives in these four subject areas are being met. The empirical work carried out shows that the transplantation system in Switzerland has developed well in the four subject areas since 2007. The actors take the guidelines into account and implement them accordingly. There is a need for mandatory regulation of the duration of the PMM before death. In order to optimise the achievement of the objectives specified in TxG, improvements at both the strategic and operational level are especially advisable. In particular, the content of the information intended for the public should be better prepared for less educated target groups and efforts should be stepped up to disseminate this information. In addition, greater attention should be paid to giving relatives enough time between the decision to discontinue therapy and the request concerning organ donation and to seek explicit consent to perform the PMM. Transplant centres should further harmonise their procedures relating to the assessment of who is added to the waiting list and to the rejection of organs. Finally, it is recommended that improvements be made to the underlying data used to assess equal opportunities where allocation to transplant centres is concerned and to evaluate the quality of transplantations.

Keywords: evaluation, Transplantation Act, achievement of objectives, implementation, population information, determination of death, preparatory medical measures, organ allocation, waiting list, quality.

Executive summary

Initial situation and goals of the evaluation

The Transplantation Act (TxG) has been in force since 1 July 2007. The Federal Office of Public Health (FOPH) commissioned a summative evaluation in 2019 in accordance with Art. 55 TxG. An overall assessment of the effects of TxG is currently not possible, as several review processes are underway and the full impact of the action plan introduced in 2013 entitled “More organs for transplantations” has not yet been felt. In contrast to these ongoing processes, this evaluation is limited to the four subject areas: informing the public, determination of death and preparatory medical measures (PMM), the allocation of organs and the quality of transplantations. The focus is on transplanting and donating deceased people’s organs.

The evaluation has two objectives. Firstly, it should be examined whether the legal objectives in these four subject areas are being met. Secondly, it should be assessed whether their practical implementation is legally compliant. Based on the findings, recommendations for possible optimisation of the legal requirements and their practical implementation should be formulated.

Method

The evaluation is based on a wide range of data sources and a combination of qualitative and quantitative methods (triangulation). For each subject area, a document analysis was the first step of the evaluation process. In addition, data evaluations were prepared on a subject area-specific basis (statistics on the use of information provided on the website of the FOPH and the school platform kiknet.ch, the Swiss Health Survey (SHS), evaluations from the Swiss Organ Allocation System (SOAS) and the annual report of the Swiss Transplant Cohort Study (STCS). In qualitative terms, between April 2019 and May 2021, a total of 16 individual expert interviews were conducted (FOPH, Swiss Conference of the Cantonal Ministers of Public Health (CMPH), STCS, Schweizerischer Transplantierten Verein, (Swiss Transplant Association, STV), four non-medical experts from listing bodies in the transplant centres and representatives of the Comité Médical des Comité National du Don d’Organes (CNDO), the national allocation body and five senior executives from the organ donation networks, Swisstransplant). In addition, four group interviews were conducted with about 30 transplant physicians from the organ-specific working groups of Swisstransplant (kidney, heart, lung and liver). In-depth discussions were held with five teachers on the teaching materials of the Confederation within the framework of information intended for the public and with eight members of deceased organ donors to gain a better understanding of the processes involved in the determination of death and the preparatory medical measures. From June to August 2020, an online survey was conducted of around 800 employees in the 14 hospitals where organs are removed in Switzerland (medical and nursing staff in intensive care units, neurologists and neuro-paediatricians involved in determining the death of patients).

Results, conclusion and recommendations

Overall, the evaluation shows that the transplantation system in Switzerland has developed well in the four subject areas since 2007. The actors take the guidelines into account and implement them accordingly. There is little need for action in terms of amending the legal

basis. In order to optimise the achievement of the objectives, however, improvements at both the strategic and operational level are advisable.¹

Subject area: informing the public

The Confederation and the cantons have a legal mandate to inform the public (Art. 61(1) TxG). The FOPH bears the main responsibility for informing the public on behalf of the Confederation, whereas the cantons have often delegated their information activities to Swisstransplant and the organ donation networks. The assessed information of the Confederation (website of the FOPH, school platform kiknet.ch and “Talk about organ donation” campaign) complies with the legal requirements. They are in principle suitable to encourage an oral or written expression of will, especially in interested persons with a high level of education. However, the results of the evaluation indicate that the population is not yet sufficiently informed. According to the results of the SHS, 38 per cent of the people who are prepared to donate have not expressed their will. The hospital staff stated that it is quite rare for relatives to have dealt with the topic of organ donation and/or to know the will of the deceased. There are also signs that people with a low level of education or a cultural background other than Swiss were not yet sufficiently focused on during the information campaign. Although the “Talk about organ donation” campaign uses simple language and well-made explanatory videos on the donation process and the expression of will, the information is only available in three national languages. The further information necessary to be able to make an informed decision, for example in the campaign brochure and on the facts and figures on the FOPH website, require a high level of reading comprehension. The explanatory video on the donation process produced during this campaign is a good starting point for presenting the complex topic in an easy-to-understand way and for encouraging informed decision-making.

Political level

No recommendation: there is no need to amend the legal basis where informing the public is concerned.

Strategic level

1st recommendation: further develop the information provided to the public by striking the right balance between good comprehensibility and the complexity of the topic

We recommend that the FOPH continue and further develop its current information activities. The approach of communicating information to different target groups in a rational and emotional way using different formats is considered to be generally appropriate.

In future, however, the FOPH should focus the information intended for the public even more on people with a low level of education and a cultural background other than Swiss, and encourage informed decision-making more broadly. The FOPH’s campaign with its current focus on “talking about organ donation” should therefore go beyond a stimulus for people to express their will.

In the evaluators’ opinion, it would be worthwhile, if this has not yet been done, to look within the FOPH for good practice examples on communicating complex topics. There are likely to be a number of subject areas dealing with similar communication challenges

¹ In the appendix A 8 to the final report on the evaluation, thematic feedback from the monitoring group is listed, which is not the focus of the report but could possibly be taken into account for further developing transplantation legislation

(e.g. strategy for antibiotic resistance) and, possibly, good solutions have been found. Current experience in communicating complex interrelationships (e.g. mRNA vaccines) during the course of the COVID-19 pandemic may also be useful. For written materials, the Federal Centre for Health Education in Germany could be used as a source of inspiration, in order to explicitly provide information on organ donation in simple language and for different population groups.²

Operational level

2nd recommendation: increase the dissemination and visibility of information intended for the public

We recommend that the FOPH increase the reach of the campaign (e.g. by showing videos on public transport screens or in the waiting area of medical practices). The use of QR codes on paper materials such as posters and stickers should be considered to provide an easy way of accessing further information on the Internet.

In addition, important elements of the information intended for the public, for example the explanatory videos, should also be translated into the most common languages of immigrants resident in Switzerland (English, Portuguese, Albanian, Serbian/Croatian and Spanish).

We also recommend that the FOPH make the school platform kiknet.ch better known to teachers. To that end, it may be possible to build on the FOPH's cooperation with the *éducation 21*³ portal.

In the evaluators' opinion, the question also arises as to whether it is an obstacle that both Swisstransplant and the FOPH provide teaching materials for pupils aged 16 and over (secondary school level II). We therefore recommend that the FOPH and Swisstransplant examine to what extent duplication exists here and whether it would not be more effective to provide the teachers with a single source of information.

Subject area: determination of death and preparatory medical measures (PMM)

The goal of the Transplantation Act, which is to guarantee human dignity, is covered in the legally binding points of the 2017 guidelines of the Swiss Academy of Medical Sciences (SAMS) on the determination of death and preparation of organ removal. The implementation of the death determination processes is carried out in accordance with the guidelines. There is no evidence that additional regulations are necessary for donation after circulatory death (DCD). However, in practice there are sometimes uncertainties as to how dying patients' palliative care is to be implemented where DCD is concerned, and it would appear as though further clarification is necessary. In practice, from the perspective of specialists and relatives, special challenges arise overall where the following ethically and legally relevant issues are concerned: limiting the duration of the PMM before death, the short time between the decision to stop therapy and the consent to donate organs, and seeking explicit consent for the PMM. Although these issues are addressed in the code of ethics sections of the SAMS guidelines and the related practical advice, they are not part of the legally binding protocols and processes (flow charts, appendices G and F). It is

² <https://www.organspende-info.de/leichte-sprache.html>, accessed on 28 July 2021. Materials will be jointly produced in different languages by means of both cultural translation and the involvement of members of the target groups.

³ <https://www.education21.ch/de>, accessed on 18 October 2021.

striking that both the legally non-binding part of the SAMS guidelines and TxG define the concept of preparatory medical measures differently.

Political level

3rd recommendation: mandatory regulation of the duration of the PMM before death

We recommend that the FOPH get both SAMS and CNDO involved in drawing up binding regulations on limiting the duration of the PMM before death in the same way as those which limit the duration of the PMM after death. The background to this is that before death, the PMM constitute an infringement of the physical integrity of organ donors, which only serves the interests of the organ recipients. In addition, the surveys have shown that an unclear, long waiting period until brain death is pronounced is extremely stressful for both medical staff and relatives. At present, the transplantation legislation only limits the duration of the preparatory medical measures after death (Art. 8 TxV); there are no legal requirements relating to the duration of the PMM before death. This aspect is relevant for implementation.

Strategic level

4th recommendation: increase respect for relatives' concerns (coming to terms with the decision to discontinue therapy; seeking approval for PMM)

We recommend that Swisstransplant provide even greater support of the following two points during implementation:

- The need for relatives to have enough time to come to terms with the decision regarding discontinuation of therapy to the extent that they can make an informed decision on organ donation.
- Taking into account the challenge of requiring relatives' explicit consent for the PMM.

The evaluation has shown that relatives do not always have enough time before making an informed decision on organ donation. However, this would be important in order to ensure their receptiveness to information on organ donation. The responsibility that comes with this decision can be traumatic for relatives. In order to counter this stress, it can be helpful to provide relatives with an information brochure in which they can subsequently reread answers to relevant questions about organ donation from relatives' points of view. Secondly, there is evidence that the relatives' legally required consent to the PMM is not always explicitly sought. In the evaluators' opinion, it is very challenging to meet these concerns in practice. We therefore recommend that greater consideration be given to this, for example as part of further training courses such as the certification "Swiss Expert in the Organ Donation Process" or within the framework of the Swiss Donation Pathway.

Subject area: organ allocation

The evaluation has not identified any systematic problems regarding discrimination in organ allocation from the time when people are put on the waiting list. On the basis of selective information from the interviews, it cannot be ruled out that inequalities occur beforehand during referral to the transplant centres.

The Transplantation Act was deliberately worded so that the transplant centres have leeway in decision-making where implementation is concerned. Therefore, there are differences between the centres, but these do not in themselves constitute a contradiction of the legal requirements. From an ethical perspective, the assessment of potential organ donors'

adherence offers the potential for discrimination. The FOPH has an insight into the allocation decisions in the SOAS and reviews them regularly. In addition, the FOPH monitors the aspects of organ allocation as part of Swissmedic's participation in the inspections of the transplant centres. In areas where transplantation medicine has certain powers of discretion – adding people to the waiting list, granting the status of “temporary contraindication” and rejecting organs – Swisstransplant and the organ-specific working groups have pushed ahead with the harmonisation of practices. They maintain a functioning exchange of ideas between the various centres in the working groups. In recent years, there has been a marked improvement in cooperation between the centres. Nevertheless, there is a need for closer collaboration. From an ethical perspective, this specifically includes the assessment of adherence, for example in relation to patients with addictive behaviours.

Political level

No recommendation: there is no need to amend the legal basis for the allocation of organs.

Strategic level

5th recommendation: push ahead with the harmonisation of the procedure in the transplant centres through a cooperative approach

We recommend that experts at Swisstransplant and in the organ-specific working groups continue to work towards a more uniform approach to the practices involved in adding people to the waiting list and rejecting organs⁴. It is the case that the differences between the centres do not constitute a contradiction of the legal requirements. However, in view of the non-discrimination objective of the TxG, further harmonisation of transplant centres' practices should be sought by means of consultations within the working groups. In this respect, the assessment of patients' addictive behaviours in particular should also be taken into consideration.

Swisstransplant and the organ-specific working groups should provide regular evidence of their corresponding efforts and progress to the FOPH as a supervisory body (e.g. as part of the annual reporting to the FOPH).

Operational level

6th recommendation: improve the underlying data for assessing equal opportunities where access is concerned

We recommend that the FOPH examine to what extent an in-depth study on the referral to the transplant centres could indicate a need for action with regard to the objective of non-discrimination. If necessary, such a study could provide a starting point for any improvements (e.g. with regard to particularly affected patient groups or regions). The referral to transplant centres is important because it is the very first step towards gaining access to the waiting list and thus for an allocation based on equal opportunities.

Subject area: quality of transplantations

The legally required data on quality (Art. 20 TxV) will be published as part of the Swiss Transplant Cohort Study (STCS). The latter is funded by the Swiss National Science Foundation (SNSF), Unimed Suisse and the transplant centres. The collection of the data requires a great deal of expenditure and time from everyone involved. The STCS is widely

⁴ Where the rejection of organs is concerned, the current state of health of the intended organ recipient, as well as the expertise of the transplantation team, are important influencing factors for the decision in the respective situation.

accepted by the transplant doctors, whereas the use of the data is currently primarily limited to research. As part of outcome research, the STCS can in principle contribute to the assessment of quality and thus indirectly to quality improvements in the transplant centres. The data currently cannot be used directly for the timely assessment of quality, for quality improvements in the transplant centres and for informing interested parties (e.g. members of Parliament).

For these purposes, above all the data on organ recipients and organ donors would have to be linked and information on organ recipients' condition before the transplantation would need to be included. The use of the data for clinical practice is also hampered by the fact that the data for the transplant centres is not available in a timely manner and that some of it lacks characteristics that are important to them. In the evaluators' opinion, it is the intention of the legislator that the data should also be useful in practice and be available to anybody interested if the former obliges the transplant centres to publish the results of the transplantations on a regular basis according to uniform criteria (Art. 27(3) TxG; Art. 20(2) of the Transplantation Ordinance (TxV)).

Strategic level (political level if necessary)

7th recommendation: consider ways to link data from the SOAS and the STCS

We recommend that the transplant centres and the Swisstransplant working groups, including the Swisstransplant branch, give the FOPH concrete details of their concerns and goals for linking data from the SOAS and the STCS. This serves to clarify to what extent the use of the data for the assessment of quality can be improved as a result in concrete terms and what requirements would be necessary for this.

On this basis, the FOPH, in cooperation with the STCS, should check the necessary legal basis for linking the STCS data with the SOAS data.

Strategic level

8th recommendation: improve the practical relevance of the STCS

We recommend that representatives of the STCS form a working group with the Comité Médical and, if necessary, other representatives of Swisstransplant to improve the practical relevance of the STCS and to prepare the data in such a way that it can be used for quality assurance and improving quality in the transplant centres and inform anybody interested.

In addition, the FOPH should examine together with this working group the validity of the guidelines on publication of the results of the transplantations laid down in the Transplantation Ordinance. In particular, it should be clarified whether and, where appropriate, which guidelines on the quality of life should be integrated into the ordinance.