The Swiss Donation Pathway

Donor recognition: legal basis and relevance in practice

Module — 1 — standard version

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CNDO
Nationaler Ausschuss für Organspende
Comité National du don d'organes

swiss transplant

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[1] DBD: Donation after brain death
[2] DCD: Donation after cardio-circulatory death
[3] SOAS: Swiss Organ Allocation System

The term "organ donation" also includes tissue donation wherever appropriate.

1.0

Summary

The Swiss Transplantation Act is the legal basis for the transplantation of organs, tissues and cells in Switzerland. It establishes the overriding objectives and governs who has which responsibilities. The highest priority is to protect human dignity, privacy and health. Any organs donated are to be donated free of charge, organ trafficking is prohibited, and organs are to be allocated fairly. No one is to be discriminated against. Responsibilities under the Federal Act on the Transplantation of Organs, Tissues and Cells, to this end, are distributed among various authorities, in particular the Confederation, additionally the cantons and the Agency for Therapeutic Products, Swissmedic. The tasks of the cantons and the persons responsible for local coordination of transplantation are defined by law. The cantons must ensure that hospitals with an intensive care unit (ICU) have defined processes for donor recognition and for taking care of the relatives of potential organ donors, and they must ensure that all processes are running properly 24 hours a day. In Switzerland, professionals in organ and tissue donation (FOGS) work as organ donation coordinators in hospitals. They have joint responsibility for ensuring that the organ donation process in Swiss hospitals runs smoothly and they are supported on the ground by local networks. The organ donation networks act in accordance with federal and cantonal regulations. The governing body for organ donation networks on the national level is the National Committee for Organ Donation (CNDO), which is responsible for guaranteeing organ donation across Switzerland. Its role is to coordinate organ donation in Switzerland and implement the strategy of Organ Donation Switzerland under the overall leadership of Swisstransplant, the Swiss National Foundation for Organ Donation and Transplantation.

The prerequisites for organ procurement in deceased persons are defined by law. Organ procurement from a deceased person may only take place if consent has been obtained and the person's death has been verified. With regard to the determination of death with a view to organ transplantation and the preparatory medical measures prior to death, the SAMS4 guidelines are legally binding (namely Item II. 3. as well as Item III. C–H).

Death can occur either through primary brain damage, in which the irreversible loss of brain function leads to death (donation after brain death – DBD), or through sustained cardio-circulatory arrest, which reduces or interrupts the blood supply to the brain until irreversible loss of brain function and loss of respiratory function occur, resulting in death (donation after cardiocirculatory death – DCD).

Preparatory medical measures are activities that are carried out exclusively for the purpose of organ donation with a view to transplantation. They therefore serve solely to preserve the organ rather than to treat the patient. They are associated with only minimal risks and burdens for the donor and are often also called non-invasive measures.

A potential donor can be identified in any hospital department. A potential donor is a patient with an infaust prognosis. This means that there is no hope for recovery or the treatment options available will not be effective. They are a patient who will die due to primary brain damage or a disease of the brain, or due to continuous cardio-circulatory arrest and the loss of respiratory function, and in whom there is no contraindication for organ donation.

These recommendations apply to all departments in Swiss hospitals, but they are particularly directed at ICUs and accident and emergency departments, due to the high incidence of patients with an infaust prognosis in these departments.

[4] SAMS: Swiss Academy of Medical Sciences.

2.0
Legal basis

2.1 Introduction

The Swiss Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Swiss Transplantation Act; Bundesgesetz vom 8. Oktober 2004 über die Transplantation von Organen, Geweben und Zellen – Transplantationsgesetz) is the legal basis for the transplantation of organs, tissues and cells in Switzerland. It establishes the overriding objectives and governs who has which responsibilities [1]. The Swiss Transplantation Act is based on Article 119a of the Federal Constitution of the Swiss Confederation of 18 April 1999 and is supplemented by regulations governing its implementation [1]. The relevant constitutional article stipulates that the Swiss Confederation legislates in the field of organ, tissue and cell transplantation, with the highest priority being the protection of human dignity, privacy and health [1]. The law states that the donation of human organs, tissues and cells is free of charge and that organ trafficking is prohibited. Particular emphasis is placed on allocating organs, tissues and cells fairly [1].

Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Swiss Transplantation Act) [1]
https://www.admin.ch/opc/en/classified-compilation/20010918/202001010000/810.21.pdf

2.2 The Swiss Transplantation Act and accompanying regulations governing implementation

2.2.1 Overriding objectives

The overriding objectives according to the Swiss Transplantation Act are as follows:

1. To establish the prerequisites for the use of organs, tissues or cells for transplantation purposes
2. To ensure the availability of human organs, tissues or cells for transplantation purposes
3. To protect human dignity, privacy and health
4. To prevent the improper handling of organs, tissues and cells

In 2016, Switzerland signed the Council of Europe Convention against Trafficking in Human Organs (Organ Trafficking Convention) in order to combat organ trafficking more effectively.

On 19 June 2020, the Swiss Parliament unanimously adopted the Convention and the legislative amendments necessary to implement it. Switzerland ratified the Organ Trafficking Convention on 21 October 2020. It has been in force in Switzerland since 1 February 2021.

Handbook for Parliamentarians: The Council of Europe Convention against Trafficking in Human Organs [2]
www.assembly.coe.int/LifeRay/SOC/Pdf/DocsAndDecs/STCE216-Handbook-EN.pdf

Swisstransplant supports this international agreement because as the Swiss National Foundation for Organ Donation and Transplantation, Swisstransplant has been entrusted by the Swiss government with the task of overseeing organ allocation in accordance with the law, which requires allocation of organs through a transparent system and strict allocation criteria. This has been explained in detail in a statement by Swisstransplant [3].

Swisstransplant statement on the ratification of the Council of Europe Convention against Trafficking in Human Organs in the Swiss Transplantation Act [3] (document only available in German)
www.swisstransplant.org/fileadmin/user_upload/Organspende/Rechtliche_Grundlagen/Stellungnahme_Swisstransplant_Ratifikation_Organhandelskonvention_Feb_2018.pdf

Although Switzerland has already been compliant with the requirements of the Organ Trafficking Convention for the most part, ratification of this convention had made it necessary to amend the Swiss Transplantation Act in some respects, including with regard to the prohibitory provisions (Articles 6 and 7) and the penal conditions (Article 69). The provision for the reporting of criminal convictions is a new provision in the Federal Act on the Transplantation of Organs, Tissues and Cells (Act 71).

To this end, the Swiss Transplantation Act (which determines the overriding objectives) establishes certain framework conditions, from which responsibilities are derived. The fulfilment of these responsibilities is delegated to the cantons. The Swiss Transplantation Act applies to the handling of organs, tissues or cells of human or animal origin and products obtained from them (transplant products) intended for transplantation into humans. For the purposes of the Swiss Transplantation Act, organs mean any part of the body whose cells and tissues together comprise a functional unit.

The Act states that there is a **general duty of care** in the handling of organs, tissues, cells or transplant products, which stipulates that any measures that may be required in accordance with the current state of scientific and technical knowledge in order not to endanger human health must be taken.

The accompanying regulations for the Swiss Transplantation Act that govern implementation include:

– The **Swiss Transplantation Ordinance:**
Regulations for the handling of human organs, tissue and cells as well as the procurement from deceased and living persons. It also defines tasks regarding organisation and coordination in connection with the maintaining the stem cell register by the FOPH.
https://www.admin.ch/opc/de/classified-compilation/20051806/201711150000/810.211.pdf

– The **Organ Allocation Ordinance:**
Provisions governing the acceptance of patients onto the waiting list as well as general and organ-specific resolutions on allocation criteria and priorities.
https://www.admin.ch/opc/de/classified-compilation/20051807/201711150000/810.212.4.pdf

– The **Organ Allocation Ordinance of the FDHA[5]:**
Detailed allocation criteria for individual organs.
https://www.admin.ch/opc/de/classified-compilation/20062074/201711150000/810.212.41.pdf

2.2.2 Tasks of the cantons

The tasks of the cantons and the persons responsible for local coordination of transplantation are defined by law [1]. The cantons must ensure that hospitals with an ICU have the defined processes listed below in place and they must ensure that all processes are running properly 24 hours a day. Furthermore, the cantons are tasked with ensuring that hospitals with an ICU notify the National Allocation Office about the person responsible for local coordination.

The defined processes to be guaranteed by the cantons in hospitals include:
1. Donor recognition and care of potential organ donors, as well as notifying the local coordinator about potential donors
2. Determination of death
3. Informing and taking care of the relatives, which includes obtaining consent for organ donation

The person responsible for local coordination in a hospital must ensure that the processes listed below are performed and coordinated correctly in the hospital in question.

[5] FDHA: Federal Department of Home Affairs

2.2.3 Tasks to be carried out in hospitals

1. Donor recognition and care of potential organ donors
2. Determination of death
3. Informing and taking care of the relatives, which includes obtaining consent for organ donation
4. Notifying the National Allocation Office about potential donors
5. Informing the tissue and cell banks about donors
6. Organ procurement

The person responsible for local coordination is also responsible for **quality assurance and monitoring of these processes.** They work together with the National Allocation Office, the transplant centres and the tissue and cell banks.

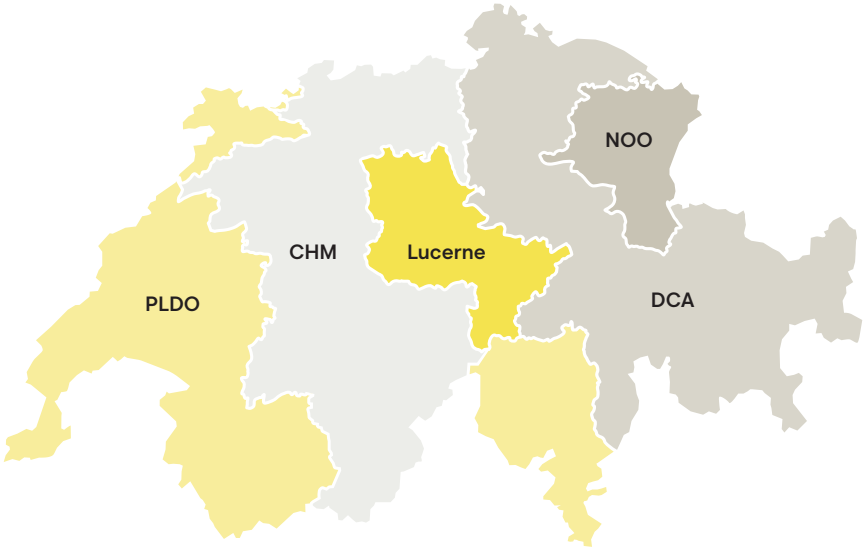
In Switzerland, FOGS work as organ and tissue donation coordinators in hospitals. FOGS work not only in ICUs, but also outside of the ICU in other areas of the hospital. They have joint responsibility for ensuring that the organ donation process in hospitals runs smoothly. FOGS are supported in the performance of their various tasks on the ground by local networks. There are five Swiss networks: Programme Latin du Don d'Organes (PLDO), Organspende Netzwerk Schweiz Mitte (CHM), Organspende Netzwerk Luzern (LU), Donor Care Association (DCA) and Netzwerk Organspende Ostschweiz (NOO) (see **Figure 1**). The organ donation networks act in accordance with federal and cantonal regulations. The tasks of the organ donation networks in connection with organ donation are listed below.

2.2.4 Tasks of the organ donation networks

1. Donor recognition and care of potential organ donors
2. Taking care of families and relatives
3. Performance recording, data verification, quality controls
4. Training and further education of medical professionals
5. Distribution of tasks between central and peripheral hospitals
6. Optimal use of resources

The governing body that oversees these five organ donation networks on the national level is the CNDO, which is responsible for guaranteeing organ and tissue donation across Switzerland. The role of the CNDO is to coordinate organ and tissue donation in Switzerland and implement the strategy of Organ Donation Switzerland (OSCH). The five organ donation networks and the CNDO, under the overarching national management of Swisstransplant, implement the requirements of their stakeholders and ensure that organ and tissue donation continue to develop in a coordinated and systematic manner. This organisational structure is intended to ensure that both regional aspects and the Switzerland-wide perspective are taken into account.

Figure 1: Organ donation networks in Switzerland.



PLDO – 16 hospitals

Programme Latin de Don d'Organes

Network Manager
Dr Marco Rusca

Cantons: FR, GE, JU, NE, TI, VD, VS

Removal hospitals
- Centre Hospitalier du Valais Romand (CHVR) (Hospital Sitten)
- Centre hospitalier universitaire vaudois (CHUV)
- Ente Ospedaliero Cantonale (EOC) (Lugano)
- HFR Freiburg – Cantonal Hospital
- Hôpitaux universitaires de Genève (HUG)
- Réseau hospitalier neuchâtelois (RHNe) (Pourtalès)

DCA – 23 hospitals

Donor Care Association

Network Manager
PD Dr Matthias Hilty/
Dr Anisa Hana

Cantons: GL, GR, SH, SZ, TG, ZG, ZH

Removal hospitals
- Kantonsspital Graubünden (KSGR) (including pediatric and adolescent medicine)
- Kantonsspital Winterthur (KSW)
- Universitätsspital Zürich (USZ)

NOO – 5 hospitals

Netzwerk Organspende Ostschweiz

Network Manager
Dr Edith Fässler

Cantons: AI, AR, SG

Removal hospital
- Kantonsspital St. Gallen (KSSG)

CHM – 21 hospitals

Réseaux de don d'organes Suisse Centre

Network Manager
Dr Sabine Camenisch

Cantons: AG, BE, BL, BS, SO, VS

Removal hospitals
- Kantonsspital Aarau (KSA)
- Universitäts-Kinderspital beider Basel (UKBB)
- Universitätsspital Basel (USB)
- Universitätsspital Bern (Inselspital) (inclusive pediatric clinics)

Lucerne – 8 hospitals

Network Manager
Dr Christian Brunner

Cantons: LU, NW, OW, UR

Removal hospital
- Luzerner Kantonsspital (LUKS) (inklusiv Kinderspital Luzern)

Since 2009, Swisstransplant as the national organisation has had the mandate from the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) to define and establish national standards for organ and tissue donation. The objective is to leverage synergies in training and continuing professional development and to harmonise communicative measures. At the network level, the five network heads and training officers are responsible for implementing the decisions made and measures decided upon at national level in their own networks and in the hospitals belonging to their networks.
The CNDO and Swisstransplant use various technical instruments to implement the objectives mentioned above.

- **"Swiss Donation Pathway":**
  This guideline contains the rules that have to be followed during the donation process. It was written as a national standard for Swiss hospitals and it is revised at regular intervals.

- **"Blended Learning":**
  An online training portal that is standardised throughout Switzerland and is based on the national guidelines set out in the Swiss Donation Pathway. Its purpose is to help ensure that donor recognition and the donation process are in accordance with quality standards.

- **"Swiss Monitoring of Potential Donors" ("SwissPOD"):**
  A database that was developed in accordance with the guidelines of the Swiss Transplantation Act for the identification of organ and tissue donors in hospitals and for monitoring the donation process. Its purpose is to optimise the quality of the donation process. Swisstransplant publishes the SwissPOD Reporting data (network comparisons / data from transplant centres) on the Swisstransplant website every semester as a PDF file. You can find it using the following link:
  www.swisstransplant.org/en/information-material/statistics/swisspod-reporting/

- **Critical Incident Reporting System (CIRS):**
  A system for reporting critical incidents in the donation process which also aims to enable mutual learning and process optimisation.

2.3 Legal prerequisites for organ procurement

The Swiss Transplantation Act defines the prerequisites for the procurement of organs, tissues and cells from deceased persons [1]. The key regulations are the following:

- Organs, tissues and cells can only be procured from a deceased person if consent has been obtained and the person's death has been verified
- If the wishes of the deceased person are not known, relatives can decide on the behalf of the deceased person
- The relatives may only be consulted about organ procurement when it has been decided to stop life support measures
- If the wishes of the deceased person are not known and no relatives are present or reachable, it is prohibited to procure organs, tissues or cells from the deceased person
- The wishes of the deceased person take priority over those of the relatives
- The relatives are not given any information about who organs are allocated to

The **extended consent solution** applies throughout Switzerland. This means that the relatives or persons of trust are involved in the decision about the procurement of organs, tissues or cells from deceased persons. According to the Transplant Ordinance, relatives are (TxV Art. 5 (2)):

a. Wife / husband, registered partner, life partner
b. Children, parents and siblings
c. Grandparents and grandchildren
d. Other persons close to the deceased person

If no documented consent or refusal is available, at least one person from among the relatives must be asked whether they are aware of the deceased person having made a declaration about donation, or whether they know of anyone who would know about such a declaration. Further details about the decision of the relatives and the persons of trust can be found in the Swiss Transplantation Ordinance (available in German only) [4].

Swiss Federal Ordinance of 16 March 2007 on the Transplantation of Human Organs, Tissues and Cells (Swiss Transplantation Ordinance) [4]
https://www.admin.ch/opc/de/classified-compilation/20051806/201711150000/810.211.pdf

2.4 Determination of death

2.4.1 Causes of brain death

The following pathologies can lead to **brain death** (listed in descending order of incidence):
- Stroke (haemorrhagic or ischemic infarction)
- Anoxic brain injury
- Craniocerebral trauma
- Other cerebral diseases (e.g. infections, intoxications)

Brain death is the irreversible loss of function of the brain, including the brainstem ("full brain death concept").

2.4.2 Prerequisites for the diagnosis of death

In Chapter 2, Section 2 of the Swiss Transplantation Ordinance, the law states that the medical-ethical guidelines of the Swiss Academy of Medical Sciences (SAMS) on "Determination of death with regard to organ transplantation and preparation for organ procurement" (version dated 16 November 2017) are to be followed with regard to the determination of death [5]. Therefore, the law does not state that the definition of death is subject to the current state of science, but rather death is to be determined according to the rules of the art of medicine.

Medical-ethical guidelines of the SAMS: "Determination of death with regard to organ transplantation and preparation for organ procurement" [5]
www.samw.ch/dam/jcr:4a69851d-bd05-49b3-a209-3ce28d66372e/richtlinien_samw_feststellung_tod_organentnahme.pdf

In the guideline, these prerequisites for the diagnosis of death are set out as follows.

Death may be due to the following causes:
1. Due to **primary** brain damage, in which the **irreversible loss of function** of the brain, including the brainstem, leads to death (donation after brain death – DBD)
2. Due to **sustained cardio-circulatory arrest,** which reduces or interrupts the blood supply to the brain until **irreversible loss of function** of the brain and the brainstem and loss of respiratory function occur, resulting in death (donation after cardio-circulatory death – DCD)

In the scenario of possible organ donation, the focus is on patients with very severe brain damage and on those requiring very substantial support of vital functions, in whom the withdrawal of said support is expected to bring about death rapidly.
Brain death is diagnosed in accordance with the requirements set out in the aforementioned SAMS guidelines [5].
Clinically speaking, the prerequisite is either irreversible brain damage of known aetiology or damage to other organs, whose cessation of function leads secondarily to death. Therefore, any conditions preventing correct clinical diagnosis of brain death must first be **ruled out** [5]. The treating team must carry out any necessary differential diagnoses for any conditions that make the evaluation of cortical and / or brainstem functions more difficult in the sense that they cause there to be only the appearance of death initially.

The following clinical conditions must be met before carrying out brain death diagnosis [5].

- Coma of known aetiology
- Body temperature >35 °C
- No shock
- No effects attributable to neuro-depressive medications
- No effects attributable to muscle relaxants
- No effects attributable to anticholinergics
- No metabolic imbalance
- No polyradiculoneuropathy (e.g. Guillain-Barré syndrome)

For further details, please refer to the corresponding reference, which also contains a checklist of **clinical signs of death** and provides information about **additional technical examinations** [5]. The SAMS guidelines take into account both DBD and DCD donors and they contain protocols for brain death diagnosis, which can be downloaded in PDF format from the SAMS website (www.samw.ch/en/Publications/Medical-ethical-Guidelines.html).

a. Death due to primary brain damage: adults and children over 1 year old
b. Death after cardio-circulatory arrest: adults, children and infants

There are some important additional **professional qualification** requirements and **structural** requirements. The impartiality of the physicians involved is essential here. This means that they must not participate either in the procurement or in the transplantation; nor may they be subject to the instructions of a medical professional who is directly involved in organ procurement or transplantation. It is also important that the medical professionals involved in caring for the dying person and the physicians involved in the determination of death are not placed under time pressure or influenced in any other way [5]. It is essential that the clinical assessment is carried out by physicians with specialist training and demonstrably adequate experience in brain death diagnosis.
For brain death diagnosis in adults, specialist training is required, either in neurology or intensive care medicine; in paediatric cases, specialist training is required in either paediatric intensive care medicine or paediatric neurology.
If a hospital does not meet the necessary professional and structural requirements for a formally correct diagnosis of brain death, a potential donor must either be transferred to a central hospital or the central hospital must provide the required expertise [5]. In the case of transfer to an organ procurement hospital, brain death diagnostics must be repeated – i.e. carried out again in accordance with the decision of the CNDO and Swisstransplant.

2.4.3 Clinical diagnosis of death

a. Death due to primary brain damage
The determination of death involves a clinical examination in which **all seven** of the following signs must be observed by two specialists using the "four-eyes principle".

1. Comatose condition (unresponsive unconsciousness)
2. Both pupils moderately to widely dilated, unresponsive to light
3. Absent vestibulo-ocular reflexes
4. Absent corneal reflexes
5. Absent cerebral responses to painful stimuli
6. Absent tracheal and pharyngeal reflexes
7. Absence of spontaneous respiration (apnoea test)

b. Death after sustained cardio-circulatory arrest
By definition, death following sustained cardio-circulatory arrest includes an irreversible loss of brain and brainstem function. This occurs as a result of sustained interruption of circulation in the brain. According to the SAMS guidelines, after cardiac arrest (absence of cardiac activity) has been diagnosed by means of transthoracic echocardiography in the subxiphoid four-chamber view, or by transoesophageal echocardiography, and after a subsequent waiting period (without resuscitation measures) of at least five minutes has elapsed, the following **six clinical signs are assessed;** they **must** all be observed [5]:

1. Comatose condition (unresponsive unconsciousness)
2. Both pupils moderately to widely dilated, unresponsive to light
3. Absent vestibulo-ocular reflexes
4. Absent corneal reflexes
5. Absent cerebral responses to painful stimuli
6. Absent tracheal and pharyngeal reflexes

Based on the fact that spontaneous respiration has not resumed within the five-minute waiting period, there is adequate evidence of its absence and therefore an apnoea test is **not** required [5].

For adults, the time of death is the exact moment when the clinical examination is completed. If an additional examination is required after the clinical determination of death, the time of death is the moment when the additional examination is completed.
For **infants,** which is to say children aged over 28 days but less than one year, or, in the case of preterm infants, more than 44 weeks' postmenstrual age, the determination of brain death involves two clinical examinations separated by a 24-hour observation period. For infants, the time of death is the moment when the second clinical examination is completed. If brain death is determined via an additional examination, the time of death is the moment when the additional technical examination is completed.
In **neonates** in Switzerland, the procurement of organs for transplantation is to be avoided in accordance with the Swiss Transplantation Act.

2.5 Preparatory medical measures

The topic of preparatory measures is dealt with in detail in the Swiss Transplantation Act, the SAMS guidelines and the CNDO guidance document "Preparatory medical measures". The SAMS document defines the scope of the guidelines as follows. The guidelines are addressed to physicians and other medical professionals caring for patients who qualify as potential deceased organ donors. They exclusively concern the requirements for organ procurement and the assessments required for it [5].

Medical-ethical guidelines of the SAMS: "Determination of death with regard to organ transplantation and preparation for organ procurement" [5]
www.samw.ch/dam/jcr:4a69851d-bd05-49b3-a209-3ce28d66372e/richtlinien_samw_feststellung_tod_organentnahme.pdf

Preparatory medical measures are activities carried out exclusively for the purpose of organ donation with a view to transplantation. They therefore serve solely to preserve the organs, tissues or cells, rather than to treat the patient. They may only be associated with minimal risks and burdens for the donor. Examples of such measures include blood typing, examination of organ function (bronchoscopy, ultrasound, coronary angiography) or measures taken to optimise organ function (circulatory stabilisation, optimisation of ventilation).

Preparatory medical measures do **not** include palliative intensive care measures such as symptom-relieving analgosedation or terminal extubation.

It is important to be aware that preparatory medical measures are divided into measures taken in the period **before** determination of death and those taken in the period **after.**

2.5.1 Preparatory medical measures prior to determination of death

Among the preparatory medical measures carried out **before** death are the continuation of existing treatments (continuation of ventilation, administration of medications and solutions to maintain circulatory function), laboratory analyses to guide treatment, and hormone replacement to maintain the "internal milieu". Existing treatments may be continued, **without** counting as a preparatory medical measure, as long as they serve purposes other than organ procurement (e.g. enabling relatives to say goodbye, palliative care).
The SAMS guidelines also include a **negative list** [5], provided below, that lists the preparatory measures that are **not permitted prior to** determination of death (the list is exhaustive):

- Placement of an arterial cannula (e.g. double-balloon triple-lumen catheter) for cold perfusion
- Mechanical resuscitation

Preparatory medical measures are furthermore **not** permitted if they could hasten death or may lead to a permanent vegetative state. Preparatory medical measures can only be carried out with **the patient's consent** (donor card, advance directive, donor app etc.). If there is **no** written record of the patient's wishes recorded in advance, the patient's wishes in this regard must be determined with the help of the relatives, as explained above. If no declaration from the patient is available, the measures that have already been taken may be continued until the relatives can be reached. If **no** relatives can be reached, or if they cannot be contacted in time, the performance of preparatory medical measures before death is **not** permitted and **organ donation must be ruled out**. The medical treatment team must respect the patient's decision for or against donation and also respect the decision of the relatives.

2.5.2 Preparatory medical measures after determination of death

After death has been determined, measures to maintain organ perfusion (cardiac massage, placement of femoral cannulae for organ perfusion, extracorporeal membrane oxygenation [ECMO]) are permitted. Because these measures cannot harm the deceased (because they are already dead), they may be carried out until the relatives' consent or refusal is available, as described in detail above.
The preparatory medical measures may be performed for **no longer than 72 hours** after the patient's death [5].

In the event of a **death not due to natural causes** or a death whose **cause is unclear,** the legal authorities must be informed in accordance with the applicable cantonal procedure in order to obtain permission for organ procurement.

2.5.3 Special circumstances in the case of death after cardio-circulatory arrest

Organ procurement in cases of death after cardio-circulatory arrest are categorised according to the type of cardio-circulatory arrest, using the Maastricht classification system [6].

Maastricht classification [6]

Category I: dead on arrival in hospital
Category II: death after unsuccessful resuscitation
Category III: death after withdrawal of life-sustaining treatment
Category IV: cardiac arrest after death due to primary brain damage
Category V: unexpected cardiac arrest in a critically ill patient

The Maastricht categories I, II, IV are organ donations following unexpected or uncontrolled cardio-circulatory arrest (uDCD; u: uncontrolled). Category III (cDCD; c: controlled) is organ donation after a planned change in the objective of treatment to palliative care. In the remainder of this document, cDCD as it is practised in Switzerland will be discussed. These patients still have preserved circulatory function, possibly with mechanical support, as long as life support measures are continued. Because the time of the change of treatment can be planned, preparatory medical measures may be instituted as soon as consent to organ donation and to preparatory measures is available. For further details, please refer to the separate module on DCD donation.

2.6 Costs involved in the organ donation process

The organ donation process involves various costs, including the costs of the work of the FOGS in the network hospitals, the costs of taking care of donors' relatives and the costs of coordinating the transport of the organ procurement surgeons. The evaluation of donors and the medical procedures that have to be carried out on donors before organ procurement are covered by the organ recipient's basic health insurance. Swisstransplant is responsible for covering any costs incurred during the donation process which are not reimbursed through the recipient's case-based flat rate of Swiss Diagnosis Related Groups (SwissDRG) and ensuring payment is made to the various partners in the hospitals who are involved. Swisstransplant performs this service on behalf of the Swiss association for joint tasks of health insurers (SVK). In 2015, Swisstransplant received a mandate from the Swiss Hospitals' Association (H+) and from the SVK for targeted financing of FOGS across Switzerland at the hospital level. Swisstransplant has a fiduciary duty to generate these financial means for the FOGS in a transparent and verifiable manner, and the foundation has been able to ensure that from 1 July 2016, specific funds are earmarked for statutory staffing resources in hospitals. In 2020, CHF 3.5 million in personnel resources will be distributed to the networks according to their catchment areas in order to finance FOGS for specific purposes – to allow them to provide training and further education in their respective hospitals with the aim of establishing national Swiss standards and the necessary processes.

3.0

Donor recognition

3.1 Introduction

As outlined in detail previously, the Swiss Transplantation Act (which determines the overriding objectives) establishes certain framework conditions, from which responsibilities are derived. The fulfilment of these responsibilities is delegated to the cantons, and they include donor recognition. The tasks of the various stakeholders in this process – the organ donation networks and their heads, the hospitals and the local coordinators in Switzerland – have also been described above in detail.
Given the situation in Switzerland, which has been outlined above, it seems appropriate to highlight here that it has been proven worldwide that countries with the highest transplantation rates (and therefore the best access to transplantation for patients) have well-established donor recognition programmes [7]. According to the 2017 international report on global organ donation and transplantation activity by the Global Observatory on Donation and Transplantation (GODT), Spain was the world leader in terms of the number of deceased donors, with an absolute number of donors of 2,183 donors per year, which corresponds to 46.9 donors per one million inhabitants. For the same period, Switzerland had an absolute number of 145 donors per year, which corresponds to 17.1 donors per one million inhabitants [8]. In 2019, the absolute number of deceased donors in Switzerland was 157 [9]. The current quarterly and annual figures for Switzerland can be found on the Swisstransplant website:
www.swisstransplant.org/en/information-material/statistics/annual-figures/.

Globally, DBD donations account for the largest share of donations after death. Up-to-date information on transplantation activity around the globe can be found on the GODT website [8].

Global Observatory on Donation and Transplantation [8]
http://www.transplant-observatory.org/

In 2017, according to the GODT annual report, there were almost 8,000 DCD donors across 25 countries worldwide. Spain had an absolute number of 573 DCD donors (12.3 per one million inhabitants) and Switzerland had an absolute number of 39 DCD donors (4.6 per one million inhabitants). In the year prior to writing (2019), the absolute number of DCD donors in Switzerland was 57 (6.7 per one million inhabitants), which is 36.3% of the total number of deceased donors in Switzerland in 2019 [9].

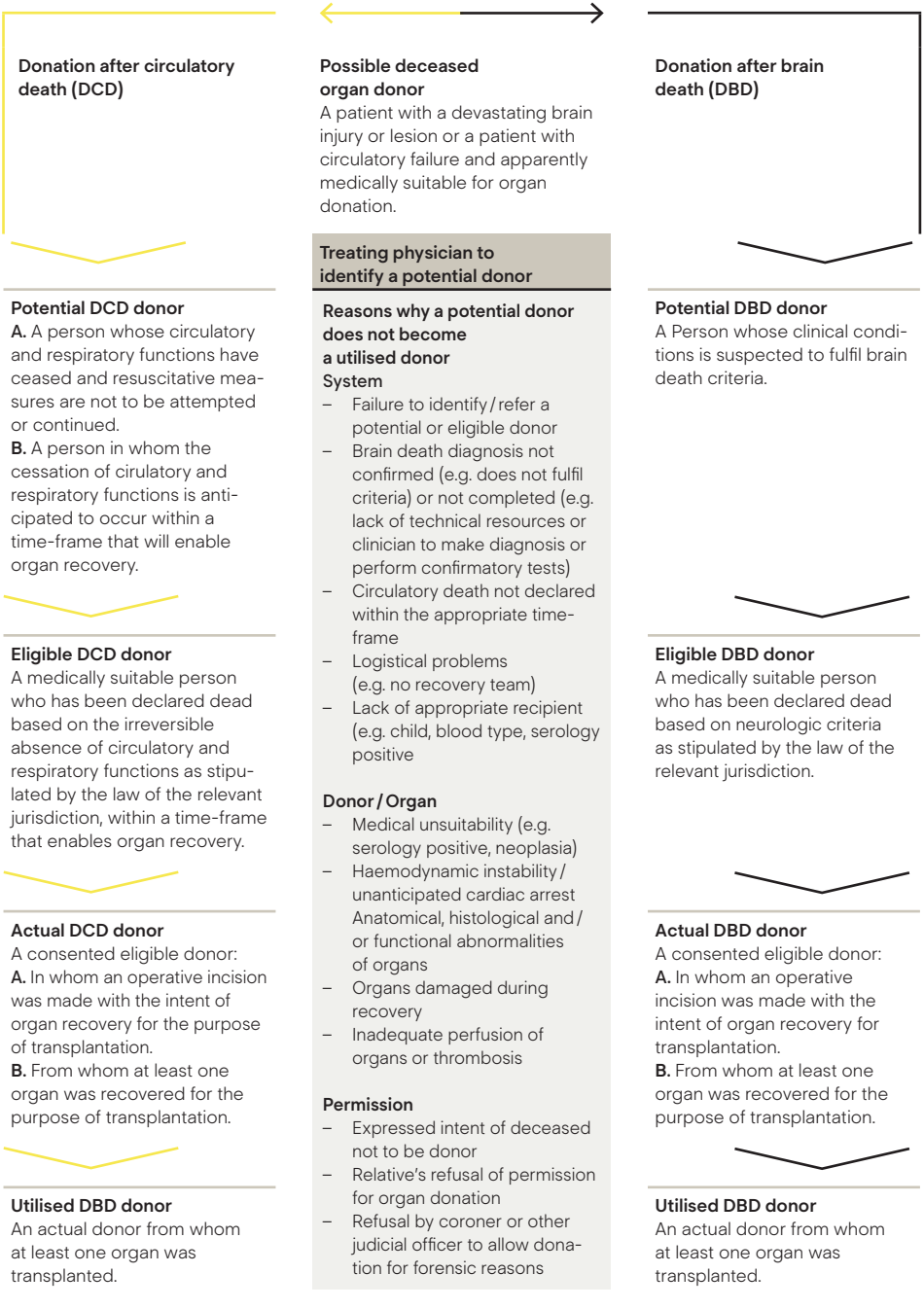
The organ donation rate, expressed as the number of organ donors per million population (PMP) is a widely used statistic, often used when comparing national organ donation activity. One reason for its popularity is that it is easy to calculate based on figures that are publicly available. It should however be noted that the donation rate is more representative of the donation activity or donation volume of a donation programme than its effectiveness or performance [10]. The donation rate does not take the potential for deceased donor donations into account when evaluating the performance of an organ donation programme. With this in mind, Julius Weiss et al. of Swisstransplant published retrospective data on deceased donors from 27 European countries plus the USA, comparing activity versus effectiveness of national organ donation programmes using the Donor Conversion Index (DCI) [10]. The DCI indicates the actual number of people who become deceased donors (donors from whom at least one organ is procured for transplantation) per 100 deaths from causes of potentially devastating cerebral damage associated with brain death [10]. Based on their analyses, the authors concluded that the DCI is a more accurate metric for assessing the performance of an organ donation programme than the organ donation rate. To optimise their performance, the national organ donation programmes should identify areas in their country where potential organ donors are not being recognised to a satisfactory extent [10].

3.2 Recognising potential donors

A potential donor can be identified **in any hospital department,** e.g. the accident and emergency department, the internal medicine ward, neurology, neurosurgery, paediatrics etc. However, these recommendations are particularly directed at all **intensive care units and accident and emergency departments,** due to the high incidence of patients with an infaust prognosis in these departments.
A potential donor is a patient with an infaust prognosis. This means that there is no hope for recovery or the treatment options available will not be effective. They are a patient who will die due to primary brain damage or a disease of the brain, or due to continuous cardio-circulatory arrest and the loss of respiratory function, and in whom there is **no contraindication** for organ donation.

It is the responsibility of the treatment team to identify potential donors and arrange transfer to the ICU. Expert intensive care treatment is essential in order to make any organ or tissue donation possible and to establish what the patient's wishes are.
In each hospital, FOGS are responsible for ensuring that the treatment team is familiar with the donor recognition processes and for providing appropriate support as explained above. "The World Health Organization (WHO) Critical Pathway for Deceased Donation" has proven a useful tool for donor recognition in everyday practice. The advantage of this guideline is that it uses consistent definitions and process descriptions, which cover both DBD and DCD donations (see **Figure 2**) [7].

Figure 2: WHO Critical Pathway for Deceased Donation, adapted according to [7]



3.2.1 Criteria for recognising potential DBD donors

A potential DBD donor is a patient with irreversible brain damage who is being considered as a potential organ donor. The key criteria for recognising a DBD donor are the following:
- Infaust prognosis with no hope for recovery or the treatment options will not be effective
- Irreversible brain damage or deep coma of known aetiology
- Clinical or radiological proof that the patient has reached brain death or that brain death may occur in the 48 hours following consent to organ donation
- **No** contraindications for organ donation

If a potential DBD donor does not reach brain death within 48 hours after consent to organ donation, they are then a potential DCD donor.

3.2.2 Criteria for recognising potential DCD donors

A potential Maastricht category III DCD donor is a patient with a confirmed change of treatment objective to palliative care who is estimated to be likely to die within 120 minutes after cessation of life support measures (including extubation) that make DCD donation possible (see **Figure 3** and **Figure 4**). The DCD organ donation process can be terminated if none of the following three values are lower than the following criteria after more than 60 minutes after the cessation of life support measures (including extubation): pH value <7.2; systolic blood pressure <70mmHg; oxygen saturation measured by pulse oximetry (SpO_2) <70%.
The decision is the responsibility of the treating intensive care physician.

Hereinafter, the term DCD donation will be used to refer to Maastricht category III DCD donation only. A Maastricht category II donation (after unsuccessful resuscitation) is also possible, but this will not be dealt with in this module. DCD donation is therefore not limited to patients with severe, irreversible brain damage – it is also relevant in the case of terminal illness, such as respiratory or cardiovascular diseases with an infaust prognosis an no treatment options.

The key criteria for **recognising a DCD** donor are the following:
- Infaust prognosis
- Confirmed change of treatment objective to palliative care
- High probability of imminent death (cardio-circulatory arrest is expected within 120 minutes after withdrawal of treatment)
- **No** contraindications for organ donation

Review article: "Donation after circulatory death" [11]
www.academic.oup.com/bjaed/article/11/3/82/257079

Figure 3: Process flow chart for DCD

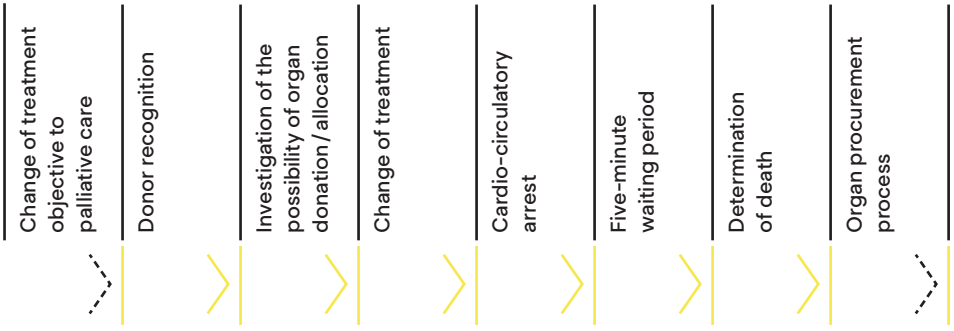
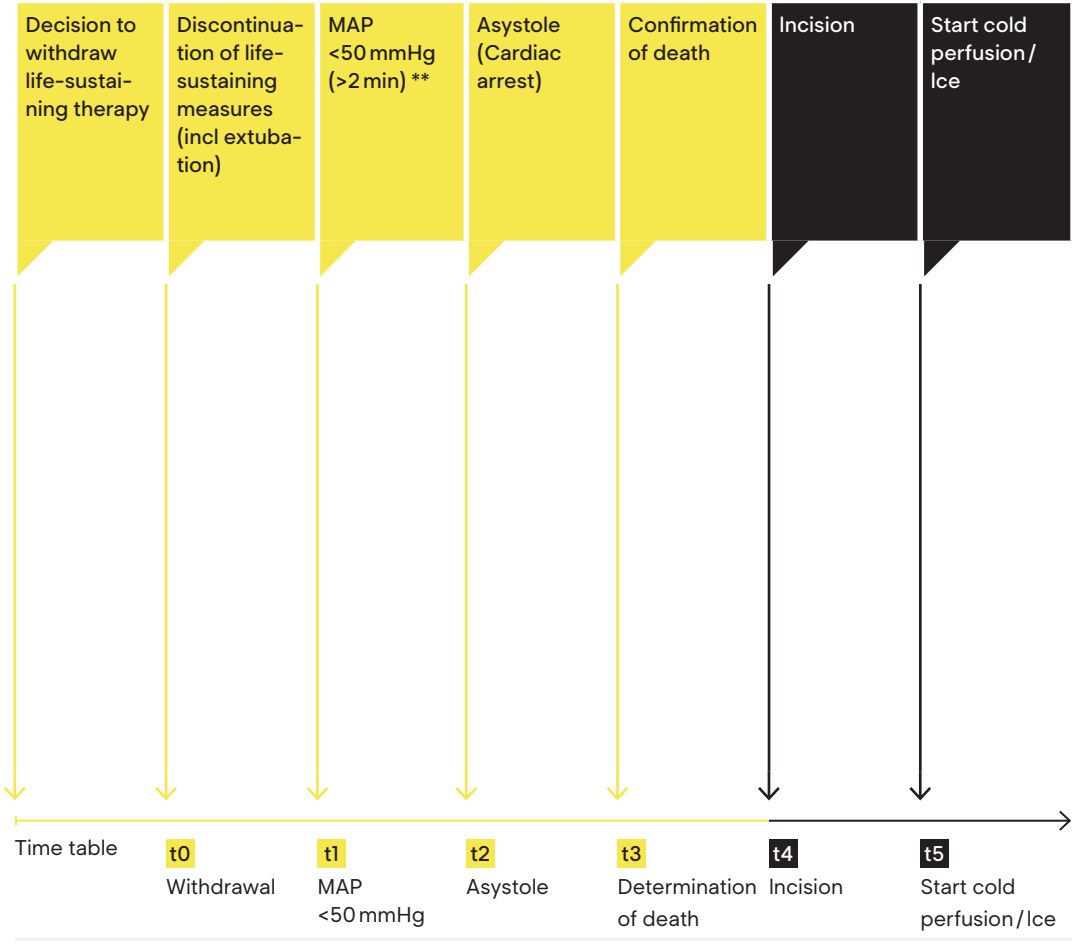


Figure 4: DCD flow chart: rapid procurement (RP)



* **Heparin administration** at t0 (300 IE / kg iv). It the likelihood of mortality is low and / or there is an increased risk of bleeding, the attending IC doctor may decide to administer the heparin later; however, the dose must be injected no later than at t1 (MAP <50 mmHg).

** **MAP <50mmHg (depending on age):** The following values are tobe used, depending on age category: **0 to 1 year: <35 mmHg; 1 to 3 years: <40 mmHg; 3 to 5 years: <45 mmHg; 5 years and above: <50 mmHg (for a minimum of 2 minutes).**

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**** Premature termination may occur, if after >60 minutes from t0 none of the 3 criteria are not met: **pH <7.2; BP syst <70 mmHg; SpO_2 <70%**

3.2.3 Contraindications for organ donation

The contraindications for organ donation are as follows:
- Neonates <28 days old or postmenstrual age <44 weeks
- **Refractory** systemic infections
- Certain degenerative diseases of the central nervous system (CNS) e.g. rabies, prion disease etc.

Nowadays, a **very differentiated** approach is required when it comes to **malignant neoplasms.** In principle, it is possible for malignant neoplasms to be transferred to immunosuppressed organ recipients from donors with a known or unknown malignant tumour, but the risk is small if the donors are selected carefully (only approximately 0.05% of organ recipients develop a tumour transmitted to them by the donor) [7]. Malignancies in the medical history of potential donors – and in some cases even an active cancer – should **not** automatically lead to a person being rejected as an organ donor. The expected risk of tumour transmission must be carefully weighed against the benefit of a possible transplantation. Advances in medicine and new scientific knowledge have made it possible to relax rules governing the inclusion of donors with neoplasms – especially in the case of localised or regionally limited tumours in the early stages. In many cases, a neoplasm that has been transmitted to the recipient can even be treated. However, **particular caution** must be exercised with regard to the detection and evaluation of malignant neoplasms in donors. A detailed donor's medical history is crucial in this context, as are laboratory tests including possible tumour markers, although routine tumour marker screening is **not** considered appropriate [7]. Imaging procedures should be carried out with great care, including CT scans of the chest, abdomen and pelvis. In some in individual cases, a tissue biopsy during organ procurement can also help to rule out a malignant tumour through differential diagnosis. During organ procurement, the procurement surgeon must also inspect all intrathoracic and intraabdominal organs (including the intestines and genitals), even if there are no plans to transplant these organs.
The recommendations that have been published thus far classify tumours according to probable transmission risk. These recommendations are based on the scientific literature, register data and expert opinions. Different countries evaluate them in different ways. The general rule is that organ donors with a history of tumours that have been treated and cured are acceptable for carefully selected recipients as long as tumour aftercare was performed with corresponding care and the period of complete absence of tumours has been well-documented. There is no international consensus on criteria for freedom from tumour recurrence – the required time free from tumours ranges between more than five and more than ten years, depending on the type and stage of tumour [7].

Primary tumours in the CNS account for up to 1.5% of causes of death in organ donors [7]. The two most important factors for the assessment of CNS tumours with regard to their risk of transmission in the context of organ donation are 1) the histologically determined WHO grade of the CNS tumour and 2) any tumour-related intervention (surgery, shunt, chemotherapy and/or radiotherapy). The general rule is, the higher the tumour grade (higher than WHO grade III) and the more interventions required, the higher the risk of transmission [7].

Malignant melanoma has been shown to have a 74% transmission rate and a 60% mortality rate in recipients [7]. The published data are still insufficient, meaning that a high transmission rate for malignant melanoma should still be assumed. In light of this fact, a superficial tumour with a tumour thickness of more than 1.5 millimetres following curative tumour resection and a recurrence-free period of more than ten years is considered an acceptable risk with low transmission rate for the recipient.

There is **no** contraindication in the case of:
- Primary basal cell carcinoma of the skin
- Cervical carcinoma in situ
- Localised, clearly demarcated tumour of low malignancy e.g. renal cell carcinoma <2 cm

Therefore, in any **cases where there is doubt,** Swisstransplant should always be asked to check whether the person may be a potential donor **before** they are categorically ruled out.

In addition, the following points should always be borne in mind:
- Advanced age is not a general contraindication for organ donation.
- Hepatitis C virus (HCV): HCV antibody-positive and PCR-negative donors can donate organs to HCV-antibody negative recipients. Organs from donors that are both HCV antibody-positive and PCR-positive can be transplanted to recipients with urgent status. In both of these cases, the recipient must provide written consent prior to transplantation. The more liberal rules on allocation have resulted in major advances in the treatment of HCV.
- Hepatitis B virus (HBV): HBV antibody-positive and HBsAg-negative donors can donate organs to HBV-antibody negative recipients. The recipient must provide written consent prior to transplantation.
- Human immunodeficiency virus (HIV): Organs may be transplanted as long as the recipient's HIV test result is also reactive. The recipient must provide written consent prior to transplantation.

The "Guide to the quality and safety of organs for transplantation" is an excellent resource that deals with the topic of the "Risk of transmission of neoplastic diseases" in detail in a dedicated chapter (#9) [7]. In all cases where there is doubt, the Swisstransplant medical service must be contacted before a potential donor is rejected for evaluation with regard to organ donation.

In **all cases where there is doubt,** it is recommended to have Swisstransplant carry out a donor evaluation.
The decision about whether a patient is medically eligible to be an organ and/or tissue donor is the responsibility of Swisstransplant.

3.3 Opening a SOAS listing

The opening of a donor listing in the computer-based national allocation system, the Swiss Organ Allocation System (SOAS), marks the end of donor recognition. The listing is opened by the donation or transplantation coordinator. The timing for opening a SOAS listing depends on the type of donation.

3.3.1 DBD donor

In the case of a DBD donation, the SOAS listing is opened after brain death is diagnosed and after the donor or the relatives has/have consented to organ donation (see the module 2: "Taking care of relatives and communication"). The donor is now a qualified DBD donor (see **Figure 2**).

A **qualified** DBD donor is a person who is medically eligible to be an organ donor (transplantable organs, no contraindications) and who has been diagnosed with brain death in accordance with the applicable guidelines.

3.3.2 DCD donor

For logistical reasons, in the case of a DCD donation, the SOAS listing is created **before** the objective of treatment is changed to palliative care and **before** the determination of death. The consent of the donor or the relatives to organ donation must be obtained **before** opening a donor listing in SOAS. The donor is now a potential DCD donor (see **Figure 2**).

A **potential** DCD donor is a patient whose cardiovascular and respiratory functions have ceased and for whom resuscitation measures are not used or have been terminated, or a patient whose cardiovascular and respiratory functions cease following withdrawal of treatment after a defined period of time, during which resumption of organ function in the recipient is possible (see **Figure 2**).

4.0
Donor reporting

4.1 Recommendations for donor reporting

Every successful donation programme is based on the systematic identification of potential donors and on donor reporting. Early donor notification is particularly beneficial, with positive effects for the entire donation process [12 – 14].
Recommendations for donor reporting are outlined below.

4.1.1 Reporting a DBD donor

If required, a DBD donor can be reported to Swisstransplant for clarification of donation potential. For as long as the donor is thought to meet the criteria for clinical signs of brain death, they are called a potential donor (see **Figure 2**).

A **potential** DBD donor is an intubated, comatose patient who is thought to meet the criteria for clinical signs of brain death.

4.1.2 Reporting a DCD donor

A DCD donor is reported to Swisstransplant as soon as the decision to change the treatment objective to palliative care has been made and consent to donation has been obtained.

A **potential** DCD donor is a patient whose cardiovascular and respiratory functions have ceased and for whom resuscitation measures are not used or have been terminated, or a patient whose cardiovascular and respiratory functions cease following withdrawal of treatment after a defined period of time, during which resumption of organ function in the recipient is possible (see **Figure 2**).

4.2 Hotlines

The Swisstransplant hotline operates **24 hours** a day. The Swisstransplant hotline can be used to clarify potential donor status, report a potential donor or check the register. For further details, please refer to the standard operating procedure (SOP) for "Donor recognition".

4.3 Transfer of potential donors

If organ procurement cannot be done at a particular hospital due to a lack of infrastructure, the patient is transferred to an organ procurement hospital with the relatives' permission. This may happen in the following ways:

- **Possible / potential DBD donors** may be transferred to an organ procurement hospital
- **Possible / potential DCD donors** may be transferred to an organ procurement hospital

In accordance with the CNDO recommendation, brain death is diagnosed in the procurement hospital or central hospital, i.e. after the transfer of the patient. Therefore, the register listing should only be called up if brain death is anticipated in the next **48 hours,** and once the infaust prognosis has been discussed with the relatives or if the possibility of organ donation has been discussed previously. For logistical reasons, it is advisable to check the register before any transfer of the patient to rule out any registered refusal of organ donation.
The transfer may be organised in conjunction with Swisstransplant if necessary. In order to avoid additional costs for the relatives and the donor detection hospitals, the costs incurred by the transfer of the potential donor and the return of the deceased person to their place of origin are covered by Swisstransplant (see the module 8: "Transport Organisation").

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Version 1.0

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Versions

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