Swiss Donation Pathway

Quality management in organ and tissue donation

Module — 12 — QM

Version 1.0 — February 2026

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

swiss transplant

CONTENT

For the sake of readability, the generic masculine form is used. However, all references to persons apply to all genders. Where applicable, the term "organ donation" also includes tissue donation.

1.0
Introduction

1.1 Necessity of quality management

Organ and tissue donation is a complex process that requires precise coordination between actors from a wide range of disciplines and organisational units.

To ensure success under these demanding circumstances, processes must be defined, monitored and continuously improved. This is where quality management comes in, forming a system of rules, responsibilities, tools and organisational culture for this purpose.

QM supports efficient organisation by

- structuring knowledge, documenting it in a comprehensible manner and ensuring that the latest version of information is always made available to all parties involved.
- continuously improving processes in line with knowledge development and experience.
- ensuring fully traceable documentation of the activities carried out.
- enabling changes to be planned in advance, properly assessed and implemented in a traceable manner.
- identifying risks proactively avoiding them.
- facilitating exchange with colleagues, including those from other hospitals.
- providing tools for systematically identify and correct the causes of errors.

1.2 Legal requirements

The introduction and maintenance of a quality management system in organ and tissue donation is not only beneficial for all parties involved, but also an obligation under the following Swiss laws, ordinances and guidelines:

- **Federal Act on the Transplantation** of Organs, Tissues and Cells [1], **Art.** 4 General duty of care: "Anyone who handles organs, tissues or cells or transplant products must take all measures necessary according to the state of the art in science and technology to ensure that human health is not endangered."
- **Ordinance on the Transplantation** of Human Organs, Tissues and Cells [2], Art. 13 Quality assurance, paragraph 1: "Anyone who handles organs, tissues or cells must have a quality assurance system in place that corresponds to the state of the art in science and technology." Article 13, Paragraph 2 also stipulates that the state of the art in science and technology is determined by national and international guidelines, recommendations from national and international professional organisations, and guidelines issued by the FOPH.
- **FOPH guideline** on Articles 13, 14, 16-18 and 51 of the Transplantation Ordinance on the handling of organs, tissues and cells for transplantation [3]. These guidelines refer to the Council of Europe's guide on safety and quality assurance in the handling of organs (EDQM Guide to the quality and safety of organs for transplantation, or **EDQM Organ Guide** for short [4]) and the corresponding guide on tissues and cells (EDQM Guide to

the quality and safety of tissues and cells for human application, or **EDQM Tissue and Cells Guide** [5]).

- The **EDQM Organ Guide** specifies four main objectives in its chapter on quality management:
  - Ensuring the quality and safety of transplanted organs
  - Ensuring that the entire process chain is carried out in an ethical and legally correct manner and in accordance with best medical practices
  - Full transparency, complete documentation and all-over traceability from donation to transplantation
  - Continuous improvement of processes and results plus increasing the number of organ donations and transplants made possible.

  To this end, the most important requirements are specified in the areas of organisation and responsibilities, staff training and further education, necessary specification documents, quality indicators, audits, document management, traceability, handling of records, investigation of incidents and deviations, risk analysis and minimisation, change management, complaints and recalls, premises, materials/equipment and contractual agreements are listed.

It should also be noted here that the partial revision of the transplantation law (passed by parliament on 29 September 2023) gives the Federal Council the option, under the new Article 24a, of making the procurement of organs, tissues or cells subject to authorisation. This applies if the quality of the procurement, in particular compliance with due diligence obligations, cannot be guaranteed. The partial revision emphasises the importance of quality assurance and provides an additional reason for all organisations involved to respect and fulfil quality management requirements.

Similarly, the partial revision adopted in accordance with Article 36 provides for the introduction of a vigilance system for serious adverse events. The system is to be operated by the FOPH, with Swisstransplant, as the designated vigilance body, taking over the investigation and documentation of reported cases. In this context, it is essential to have access to regulated structures and responsibilities, established processes and fully traceable records. This further underlines the need for effective quality management among all actors involved in organ and tissue donation (see also EDQM Organ Guide [4]; Chapter 16.3.3.).

1.3 Objectives of the module

With the ECHONET project (Extension of Compliance and Harmonisation of Organ Donation Processes in Networks), launched in 2024, Swisstransplant and the CNDO are further developing quality management in organ and tissue donation processes.

Inspections carried out in the organ donation networks/donation coordination centres revealed that without specific knowledge and sufficient resources, the quality management requirements listed in the EDQM Organ Guide are difficult to implement.

As a first step, the role of "Quality Management Specialist for Organ Donation Networks" (Q-FOGS) was introduced in 2025. This role is intended to support network hospitals in implementing adequate quality management systems (and also to contribute to the development of harmonised processes/documents throughout the entire organ donation process).

As a further measure, it was decided to provide a Swiss Donation Pathway Module on quality management in organ donation as a knowledge base, specifically adapted to match with the structures in Switzerland.

The **general information** in the Module (e.g. good documentation practice) is aimed at all medical professionals involved in organ donation. The **detailed information** (e.g. step-by-step process flow of an internal audit) is specifically aimed at medical professionals who play an active role in setting up and/or maintaining the quality management system.

> The QM requirements are defined in the EDQM Organ Guide at a normative and abstract level. This reference work provides specific additional information and recommendations on how to implement them in practice.

2.0
Structures

Structures are of central importance in quality management because they create the basis for a systematic and targeted approach.

2.1 Swisstransplant

Swisstransplant is the Swiss National Foundation for Organ Donation and Transplantation. On behalf of the Federal Office of Public Health (FOPH), it has been responsible since 2007 as the National Allocation Office for the lawful allocation of organs to recipients and maintains the waiting list. Swisstransplant organises all activities related to organ allocation at the national level and works closely with European allocation organisations. Swisstransplant also regularly compiles statistics on the number of organ donors, transplants and waiting times.

Since 2009, Swisstransplant has been commissioned by the Swiss Conference of Cantonal Health Directors to coordinate the cantons' tasks in the field of organ and tissue donation at national level as laid down in the transplantation law, to ensure these tasks are carried out in the organ donation networks and to exploit synergies.

In addition, Swisstransplant is responsible on behalf of the health insurance companies (Swiss association for joint tasks of health insurers, Solothurn) and the H+ Swiss hospitals association for settling the costs of the donation process that are not covered by the SwissDRG flat rates for the recipient with the partners involved in the donation process according to clear guidelines and tariffs.

Structure of Swisstransplant

The **foundation board** is the highest body of Swisstransplant. It is responsible for the strategic management of the organisation. The foundation board is composed of experts from the departments of medicine, law, ethics, politics, insurance, patient organisations and hospitals.

The Swisstransplant **office** is responsible for all administrative and operational processes and tasks relating to organ and tissue donation. The following two core departments are particularly noteworthy:

- The **National Coordination** allocates available donor organs to recipients after consultation with the transplant centres, organises and coordinates all activities related to allocation at national level and cooperates with foreign allocation organisations. The National Coordination operates 24 hours a day, 365 days a year, to ensure that all organ donations run smoothly and in accordance with the law. The department also maintains the waiting list of patients awaiting organ transplants.
- The **Donation Management** works closely with the "professionals in organ and tissue donation" (FOGS), who act as coordinators for organ and tissue donations in hospitals and are funded by Swisstransplant for this specific purpose in accordance with the contractual basis. In addition to working closely with the committees and medical professionals, Donation Management is responsible for various technical tools. The Swiss Donation Pathway contains the guidelines necessary for the donation process and has been designed as a national standard for hospitals. Blended learning is a nationally

standardised training programme based on the guidelines of the Swiss Donation Pathway. The SwissPOD (Swiss Monitoring of Potential Donors) database, developed in accordance with the guidelines of the transplantation law, enables the identification of organ and tissue donors and the tracking of the donation process. The Critical Incident Reporting System (CIRS) serves as a reporting system for critical incidents in the donation process and aims to promote mutual learning and process improvement.

The office is supported by two committees: the National Committee for Organ Donation (**CNDO**) and the Medical Committee (**CM**).

The **National Committee for Organ Donation (CNDO)** is responsible for organ and tissue donation in Switzerland on behalf of the Swisstransplant Foundation. The committee is committed to ensuring a high-quality donation process in Switzerland that focuses on ethical principles and complies with legal requirements. The CNDO is composed of

- **Steering Committee (StA):** Handling tasks related to the management and development of organ donation networks. Developing decision-making bases for the CNDO and the Foundation Council.
- **Operational Core Team (OKT)**: Carrying out the tasks assigned by the steering committee. Optimising and developing processes in organ and tissue donation.
- **Technical committees**: Developing expertise on specific tasks. Technical committees on DCD, paediatrics and cornea donation are currently in place.

The **Medical Committee (CM)** is Swisstransplant's medical committee, which deals with issues relating to transplant medicine. It discusses the technical concerns of experts in transplant medicine. Within the CM, there are dedicated working groups for individual organs (heart, lung, liver, kidney, pancreas and intestine) as well as individual working groups for the specialist areas of procurement and transport, infectiology, transplant coordination and living organ donation.

2.2 Organ and tissue donation networks

Hospitals with intensive care units in the vicinity of Switzerland's major transplant centres have joined together to form five regionally organised donation networks.

Programme Latin du Don d'Organes (PLDO), Schweiz Mitte (CHM), Transalpina (TA), Donor Care Association (DCA) und Netzwerk Organspende Ostschweiz (NOO)

Figure 1 : Organ donation networks

The medical professionals involved in organ and tissue donation in the networks are funded by Swisstransplant on behalf of the Conference of Health Directors. The Swisstransplant Foundation is responsible for ensuring that the contractual requirements for organ and tissue donation are implemented in a standardised manner throughout Switzerland and that synergies are exploited wherever possible. The foundation reports to the Conference of Health Directors every six months and is responsible for implementing the contractual requirements.

The goal of the donation networks is to ensure the identification, notification and care of organ donors and their relatives in order to increase the number of organs and tissues available for transplantation.
The networks also have the task of supporting hospitals in introducing all procedures related to organ and tissue donation, ensuring the training of medical and nursing staff and assisting in the implementation of a quality management system. In doing so, synergies must be exploited and the directives and recommendations ultimately issued by the foundation board must be implemented strictly.

Network heads

Each network is headed by a manager who ensures that decisions and measures agreed upon at the national level are implemented within their own network and who governs the tasks attribution between the central hospital and the affiliated hospitals. Network heads also ensure that the personnel resources available to a network (especially FOGS) are adequately distributed among the individual network hospitals. In addition to allocating human resources, recording performance and monitoring processes in the network hospitals, the network heads are also responsible for periodic reporting to the CNDO and the Swisstransplant foundation board. This reporting includes milestones, analysis of indicators and the cash flow statement for the network. In an annual meeting led by the director of Swisstransplant, the goals and implementation of measures in the respective network are evaluated and further reported to the foundation board.

Network coordinators

The network coordinators support the FOGS/hospitals in implementing the goals set by the network head and the CNDO, ensure the ongoing exchange of knowledge and expertise within the network, and are also responsible for providing training and continuing education programmes for medical and nursing staff in the intensive care and emergency departments of the network hospitals.

Professionals in organ and tissue donation (FOGS)

Around 170 medical professionals specializing in organ and tissue donation in hospitals with accredited intensive care units implement the guidelines adopted by the CNDO, thereby ensuring the organ and tissue donation process from detection to procurement:

- Donor recognition and support for relatives
- Determination of death
- Informing next of kin and taking care of relatives, including obtaining consent
- Notification of the donor to the Swisstransplant National Coordination
- Cooperation with tissue and cell banks
- Organ procurement

Quality management professionals for organ donation (Q-FOGS)

To support network hospitals in implementing an adequate quality management system and to develop harmonised processes and documents throughout the entire organ and tissue donation process, at least one person responsible for quality management is available within each network. The main tasks of this function are:

- Process and document control
- Auditing and other opportunities for continuous improvement
- Deviation management, CIRS, vigilance, complaints
- Change management (change control)
- Collection, evaluation and reporting of quality indicators and key figures
- Risk management (risk analysis, risk mitigation)
- Collaboration on the harmonisation and standardisation of quality-related processes and documents within the network and at national, cross-network level

2.3 Hospitals

Currently, a total of **73 hospitals** (grouped into **five networks**) form the basic framework for identifying and caring for organ donors, known as **detection hospitals**. Fifteen of these are capable of performing organ procurement, known as **procurement hospitals**. Six of the 15 organ procurement hospitals are also **transplant centres**, where, in addition to organ procurement, transplantations on recipients are also performed.

Detection hospitals

Each donor detection hospital has specially trained personnel (FOGS) who guarantee and ensure the following processes:

- Identification of potential donors
- Care and treatment of donors, together with the intensive care unit
- Informing and caring for relatives, including obtaining consent
- Transfer of the donor to an organ procurement hospital
- Quality assurance and control of processes in the hospital
- Recording of all deaths in intensive care and accident and emergency departments in SwissPOD.

Procurement hospitals

Each organ procurement hospital has a dedicated organisational unit (donation coordination) that guarantees and ensures the following organ donation processes around the clock:[1]

- Identification of potential donors
- Care and treatment of donors, in conjunction with the intensive care unit
- Informing and caring for relatives, including obtaining consent
- Conducting discussions with relatives to evaluate donor suitability and provide information about the donation process
- Diagnostic investigations
- Accompanying organ procurement
- Recording requirements and traceability
- Conditioning and transport of donated organs
- Quality assurance and control of hospital processes
- Recording of all deaths in intensive care and accident and emergency departments in SwissPOD.

Transplant centres

In addition to local donation coordination, which handles tasks related to organ procurement (see organ procurement hospitals), each of the six transplant centres also has a transplant coordination team on site that takes care of the following tasks:

- Listing patients on the national waiting list for organ transplantation
- Forwarding organ offers to the responsible doctors
- Organising the transplantation

In the *CHM* and *NOO* networks, donation and transplantation coordination are carried out by the same staff, whereas the *DCA* and *PLDO* handle these tasks separately. Due to the lack of a transplant centre in the network, *TA* only covers the donation side.

[1] The networks can organise an on-call service. This means that a donation coordinator does not have to be on site at all times.

3.0
Processes, documents and records

3.1 Definitions

The definitions below were drawn up based on the EDQM Organ Guide [4], ISO 9000:2015 [6], ISO 9001:2015 [7] and EudraLex Vol. 4 Part I [8].

- Process: Coordinated interaction of people, machines and materials in a specific, repetitive sequence of work steps. At the end of the process, there is either a product, a service provided or a follow-up process.
- Document: Structured information carrier containing descriptions of processes/activities/products or requirements for them.
- Process and document control: Controlled processes and documents are characterised by the fact that their life cycle is regulated from design to validation to archiving. Controlled processes and documents undergo review and approval workflows prior to publication, are versioned, periodically checked for currency, adequately protected against loss and alteration, and are available in readable form at all times.
- Records: Records serve as evidence. Records serve as proof of activities performed or as proof of compliance with requirements. Records cannot be changed retrospectively and are therefore not subject to versioning.
- Process and document management system (PDMS): Software for creating and managing processes and documents. Corresponding tools offer functionalities for modelling the process map, for elaborating the individual processes (flowchart editor), for linking applicable documents with processes or individual process steps, for controlling processes and documents, including automatically triggered workflows for periodic review and notifications for new or changed specifications (requesting read & understood confirmation) and much more. All information required for process execution is available quickly and in an understandable manner. It is also ensured that when changes are made to processes, the impact on existing relevant documents is evaluated (and vice versa). In addition, modern systems also allow records to be created and stored.
- Owner / reviewer / approver: The owner is a qualified person who is very familiar with the process or document because they use it themselves in their daily work. There is only one owner per process/document.

  The reviewer is usually a second qualified person who is familiar with the process or document from their own experience. Several reviewers can be appointed.

  Finally, every new or changed process/document must be approved. The approver is usually a manager who takes control and responsibility for the processes and documents. However, several approvers may be appointed.

  The owner, reviewer and approver must be at least two different persons. This ensures that the dual control principle is adhered to when creating or changing quality-relevant processes and documents.

3.2 Processes

A regulated process landscape allows for increased transparency and traceability in procedures and reduces misunderstanding.

> As a positive side effect, it makes it easier for new employees to get started, as they can build on existing knowledge, thus shortening training periods.

The processes to be regulated in organ donation are listed in the EDQM Organ Guide. To supplement this list, instructions are provided below on how individual processes can be created, linked together and structured hierarchically. The functionalities of software solutions for efficient process management are also outlined.

3.2.1 Structuring / process map

For hierarchical structuring and visualisation of the overall overview, processes are embedded in a multi-level process map. A widely used standard that is well suited to the field of organ donation is based on the following three levels in the process map:

Top level: Process family. At the top level (process family), a distinction is made between management, core and support processes.

Management processes include all processes within an organisation that are necessary for its steering and monitoring. According to the EDQM Organ Guide ([4]; Chap. 18.5.1.), these are the following processes:

- Strategic planning
- Organisational structure, functions and responsibilities
- Resource planning
- Premises
- Training and development, competence assessment
- Research areas / scientific exchange

Core processes include all processes directly related to value creation or service provision. According to the EDQM Organ Guide ([4]; section 18.5.2), these are:

- Donor recognition
- Donor evaluation/characterisation
- Certification of death
- Donor treatment
- Taking care of relatives
- Organisation of organ procurement
- Organ procurement
- Organ preservation, packaging and transport
- Communication with regional and national authorities

Support processes include those processes that create the necessary framework conditions for the core processes, but do not themselves generate any direct added value (e.g. IT, quality management, maintenance). According to the EDQM Organ Guide ([4]; section 18.5.3.), these are:

- Document and process control
- Handling and traceability of records
- Change control
- Deviation management
- Auditing

- Risk management
- Qualification/validation of premises, equipment and materials
- Monitoring of (contractually) outsourced activities

Middle level: Process groups. Processes with similar themes are grouped together (e.g. organ donation processes, tissue donation processes, maintenance processes, material management processes, HR processes, IT processes, etc.).

Lowest level: Individual processes (such as procedures for unusual death in the context of organ donation, heart valve procurement for EHB, follow-up care for relatives, document control process, etc.).

Example: The **individual process "donor detection"** regulates the identification of potential donors in intensive care units or emergency rooms and the notification towards the donation coordination team. Together with other thematically related processes (such as "clarification of consent", "determination of death", "donor treatment", etc.), this process belongs to the **process group "organ donation".** The "organ donation" process group, together with other process groups such as "tissue donation", belongs to the **process family "core processes"**.

3.2.2 Creation/control

The following metadata/characteristics must be defined for each new process to be created

- Number (optional) *
- Title
- Responsibilities (owner / reviewer */ approver *)
- Version and status *
- Validity and next periodic review (date) *
- Scope (users, subscribers)
- Input (optional)
- Output (optional)
- Benchmarking variables (optional)
- Critical success factors (optional)
- Normative bases / applicable documents (optional)

(* depending on the QM software used and its configuration, these fields are filled in automatically or must be defined manually):

Once this basic framework is in place, the new process can be filled with content information. A flowchart is usually used for this purpose. The flowchart visually shows the workflow step by step, names (links) the necessary basics/documents and responsibilities, and refers (links) to other processes with which there are interfaces.

Once a process has been created, it is reviewed and then approved. The most common QM software tools automatically adjust the lifecycle/status, versioning and validity date of processes.

If this functionality is not available, it can also be controlled manually.

Versioning is usually done according to the vX.Y scheme, where vX.0 represent released main versions (e.g. v5.0) and versions with Y≠0 represent versions that are currently under revision (e.g. v5.13). Once revised versions have successfully passed through the release workflow, the version changes to the next higher main version (e.g. v5.13 becomes v.6.0).

The life cycle/status of a process can in turn be divided into categories such as "Draft", "Authorised", "Valid" and "Archived".

If processes are changed, it must also be ensured that a change history is always documented. Likewise, all processes must be reviewed periodically. After a defined period of time (e.g. one year after becoming valid), the owners must review the content of the processes to ensure that they are up to date and practicable. If changes are necessary, a new version must be created. If not, the current version remains valid until the next periodic review (or interim revision).

3.2.3 Software solutions for process management

In order to operate efficient process management, an appropriate software solution (process and document management system, PDMS) should be used.

- By using a graphical editor (flowcharts), individual processes can be recorded quickly and efficiently, and responsibilities and applicable documents/basis for the individual work steps can be assigned directly.
- Predefined review and approval workflows ensure content verification and hierarchical approval for new/changed processes.
- Processes are automatically versioned, the modification history is recorded and previous versions are archived.
- Reminders ("notifications") are automatically triggered for periodically scheduled checks.
- Users/user groups are informed about the release of new/changed processes. A read & understood confirmation can also be actively requested.
- Processes can be easily embedded on other platforms (e.g. links on the intranet/extranet).
- Extensive full-text search.
- Comprehensive functionalities in the user management and role assignment (e.g. read-only user, creator, reviewer, approver, admin).

If no corresponding PDMS is available, processes should at least be visualised as flowcharts in the standard operating procedures (SOPs) (see chapter 3.3.1). However, this solution is static and does not allow for adequate linking of processes with each other.

3.3 Documents

According to the EDQM Organ Guide ([4]; Chapter 18.5.3.2.), written specification documents must exist for all activities in the organ donation process in order to ensure transparency and traceability. These include SOPs (Standard Operating Procedures) as well as other supporting documents such as work instructions, checklists or templates for records (e.g. template for documenting periodic LifePort function tests). In addition to the activities directly related to organ donation, written guidelines on quality management must also be drawn up (e.g. quality manual[2] , SOP for process and document control, SOP deviation management, etc.).

The following chapters specify how documents are created and controlled. They also show how appropriate software solutions (document management systems) can provide support in managing an extensive document landscape.

3.3.1 Creation/control

In order to ensure a consistent document landscape, templates for the individual document types must be created. These can be, for example:

- Policy[3]
- Standard Operating Procedure [4]
- Work Instructions [5]
- Checklist
- Form
- Report

Sufficient space must be provided in the headers and/or footers of the templates for the logo of the hospital/donation network and for metadata (document name, version, status, validity date, document owner and page numbers).

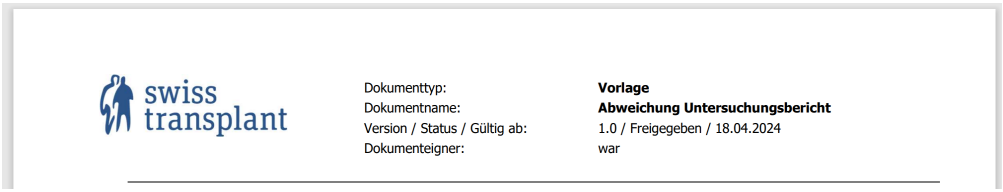

Figure 2 : Example of a header for a controlled document

The corresponding templates should also contain the style elements of the corporate design to be used (such as text format templates, layout parameters, etc.). It is also a good idea to define

[2] A quality manual is a controlled document that contains information on the structure of the organisation, the responsibilities and competencies of the respective organisational units, the IT tools used, and a general overview of the management, core and support processes to be applied. In addition to the general overview, the QM processes are described in more detail and specify which systems are used (e.g. how deviations are handled, how documents are updated and approved, which normative basis/legal standards are to be respected, etc.).

[3] Overarching guidelines defining the general intentions and orientation of an organisation with regard to topics such as culture, quality, security and strategy (*e.g. IT policy*).

[4] Describes the purpose and general steps of a process to ensure consistency and compliance throughout the entire process (*e.g. SOP for Multi-Organ Retrieval DBD*).

[5] Detailed, step-by-step instructions for a specific, individual task within a process or a definable subject area within a process (*e.g. instructions for preparation, use, cleaning and periodic functional testing of the LifePort Kidney Transporter*).

the chapter structure for the individual document types so that documents of the same type have an uniform structure.

Example chapter structure SOP:

1. Purpose
2. Scope
3. Flowchart (if not shown separately in a process, see also *chapter3.2.3*)
4. References
5. Definitions and abbreviations
6. Responsibilities
7. Procedure
   - 7.1 Subchapter on the procedure
   - 7.2 Subchapter on procedure
   - 7.X Subchapter on procedure
8. Modification history

A new document is created based on a template and assigned the following metadata/characteristics:

- Number (optional)*
- Title
- Responsibilities (owner / reviewer */ approver *)
- Version and status *
- Validity and next periodic review (date) *
- Scope (users, subscribers)

(* depending on the QM software used and configuration, these fields are filled in automatically or must be defined manually)

The document can then be created and edited. Once completed, the review and approval process is started. With most common QM software tools, the status, versioning and validity date of documents are adjusted automatically. If no such software is available, manual adjustments must be made as described in *the chapter "3.2.2 Creation/Control*".

As with processes, all changes to documents that result in a new valid version must be tracked in a change history. For documents, it is advisable to include a chapter for this directly in the template. Alternatively, depending on the QM software used, the change index can also be entered in a corresponding input mask.

All valid documents must be reviewed periodically by the owner (e.g. no later than 1 year after becoming valid).

3.3.2 Structuring / document hierarchy

Figure 3 (normative level, strategic level, operational level, detail level).

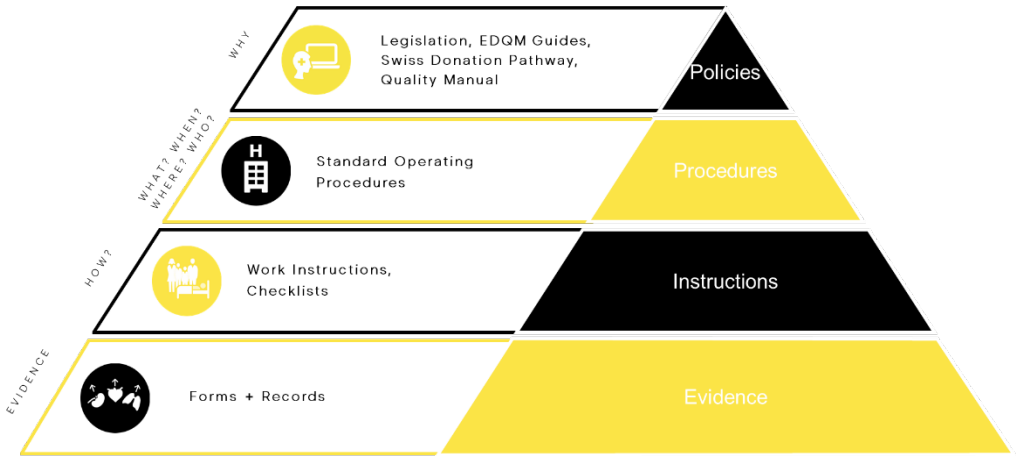

Figure 3 : Document hierarchy pyramid

A corresponding hierarchy has the advantage that generally applicable requirements only need to be described once centrally and do not have to be listed again in every document below it (redundancies always carry the risk of inconsistencies if the documents are updated independently of each other over time).

The hierarchical structure also goes hand in hand with different requirements for document ownership and approval.

3.3.3 Software solutions for document management

A complex process such as organ donation brings together a wide variety of specialist areas such as medicine, logistics, communication, technology and laboratory work. This requires a comprehensive and regulated documentation basis for all medical professionals involved. In order to manage the document landscape efficiently and cleanly, an appropriate software solution (process and document management system, PDMS) should therefore be used. Such systems support the efficient creation and maintenance of controlled documents.

- Documents can be created directly from stored templates and supplemented with the necessary metadata.
- Predefined review and approval workflows ensure content verification and hierarchical approval for new/modified documents.
- Documents are automatically versioned, the modification history is recorded and previous versions are archived.
- Reminders (notifications) are automatically triggered for periodically scheduled checks.
- Users/user groups are informed when new/modified documents are approved. A read & understood confirmation can also be actively requested.
- Documents can be easily made available on other platforms (e.g. links on the intranet/extranet).
- Extensive full-text search (including OCR, optical character recognition)
- Comprehensive functionalities in the user management and role assignment (e.g. read-only user, creator, reviewer, approver, admin).

3.4 Records

3.4.1 Good documentation practice

Records, whether created electronically or by hand, must comply with good documentation practices ([4], section 18.5.3.2). A suitable standard for this are the rules on data integrity used in the pharmaceutical industry [8], such as ALCOA+ [9], which can also be applied to handwritten and electronic records in organ donation.

Attributable: It must be possible to assign who performed an activity and when (e.g. date/time and visa after each completed work package).

Legible: Handwritten entries should be legible and made with indelible/non-erasable ink (e.g. blue ballpoint pen). Uniform, clear language should also be used (no abbreviations or phrases that could be misunderstood).

The legibility of words and numbers is far less problematic with electronic records. However, it must be ensured that the selected data type is universal and can still be read years or decades after the record was made.

Contemporaneous: Documentation must take place at the time of the activity and directly at the location where it occurred.

Original: Information should always be available in the original record. The use of uncontrolled copies/reproductions should be avoided. Values transferred in other records (such as the information of the blood group noted down on the coordination protocol) must be transferred from the original file (e.g. blood group card) or from a certified copy. The same applies to attachments that are enclosed with the records. Furthermore, measures must be taken to prevent unauthorised access to or changes to records so that the integrity and authenticity of records is guaranteed throughout their entire life cycle.

Accurate: Entries should be correct and accurate. Read out/transferred values should be recorded unedited/unrounded. Any change to an entry in a document should be signed and dated; the change should still allow the original information/values to be read. If necessary, the reason for the change should also be noted.

(**+**) Complete: The records (and their attachments) should contain all information so that a complete picture of the activities carried out can be reconstructed at any time.

(**+**) Consistent: The sequence/chronological order of activities contained in the records must be logical and consistent with other relevant documents/records.

(**+**) Enduring: Records must be stored securely for the entire statutory retention period (access-controlled archive including fire protection, backup & restore of electronic files, etc.).

(**+**) Available: Records must be made quickly and easily available throughout their entire life cycle (e.g. for audits and inspections, vigilance cases, etc.).

3.4.2 Scope of necessary records

Handwritten and/or electronic records must be created to ensure a complete and traceable reconstruction of all steps and data that affect the quality and safety of donors/organs/recipients. This includes, in particular, the following records (EDQM Organ Guide [4]; Chapters 18.5.1.1./18.5.2.1./18.5.3.2./18.5.3.3./ 18.5.3.8):

- Donor identification
- Consent / discussion with relatives (informed consent)
- Brain death protocol
- Evidence of all clinical and analytical tests for donor and organ characterisation (e.g. laboratory findings, CT reports, etc.)
- Procurement protocol
- Perfusion records (including identifiers or serial numbers of equipment used as well as the lot numbers of kits/perfusion solutions used)
- Coordination protocol (also known as donation protocol): documentation of the work carried out by the local donation coordination team. In conjunction with the data entered in SOAS and hospital information systems, full traceability (and reconstruction) of the process from donor identification to the dispatch of the retrieved organs is guaranteed.

The following records must also be kept by the donation coordination/organ donation networks:

- Personalised and signed job descriptions
- Confidentiality agreements
- Proof of training and further education
- Records generated in the course of the following QM processes:
    - Complaints / incidents / deviations (e.g. investigation reports)
    - Change management
    - Auditing (e.g. audit reports)
    - Risk analyses/risk management
- Evidence/records relating to the maintenance, surveillance, monitoring, cleaning and calibration of technical equipment.

4.0
Change management (Change Control)

4.1 Definition

Intended changes to systems, processes, procedures and materials can have far-reaching implications for the safety of the donor/recipient or the effectiveness of organ and tissue transplantation.

The Change Control process provides a structured approach to ensure that changes in the organ donation process that (may) impact on the quality and/or safety are planned, evaluated and approved prior to their implementation (EDQM Organ Guide [4]; Chapter 18.5.3.6.). The process also ensures the coordinated implementation of the defined measures and provides complete, traceable documentation to the entire change, from planning up to completion.

In contrast to general project management, the Change Control process strictly specifies the steps to consider, the documentation to be created and the roles and responsibilities of the persons involved.

Change Control is not generally required for the continuous revision of version-controlled documents. Such changes are tracked directly in the document's modification history. However, adjustments to version-controlled documents can also result out of larger procedural changes that need to be tracked as Change Control.

Examples of Change Control: implementation of a new procurement technique (aNRP) / change of a service provider (laboratory, transport, eye bank, etc.) / procurement of new organ perfusion machines.

Examples of other modifications that do not required to be tracked as change control: renewal of office infrastructure / periodic revision of specification documents / information campaigns for the public.

4.2 Responsibilities

Reporting person: Identifies the need for a change to systems, services, processes or procedures and opens a request for this.

Person responsible for implementation: Responsible for planning, implementing and documenting the change.

Management: Review of the benefits, necessity, impact and risk of the change. Allocation of resources. Review and approvals before and after implementation.

Quality Management (QM) department/responsible: Ensuring formal requirements are met, providing editorial support, reviewing the benefits, necessity, impact and risk of the change. Review and approvals before and after implementation.

Subject matter expert (SME): If necessary, contributes subject matter expertise from areas of knowledge not already covered by the person responsible for implementation, management or the QM department.

4.3 Process flow

The change control process is divided into several logical phases. These are listed below (exemplary).

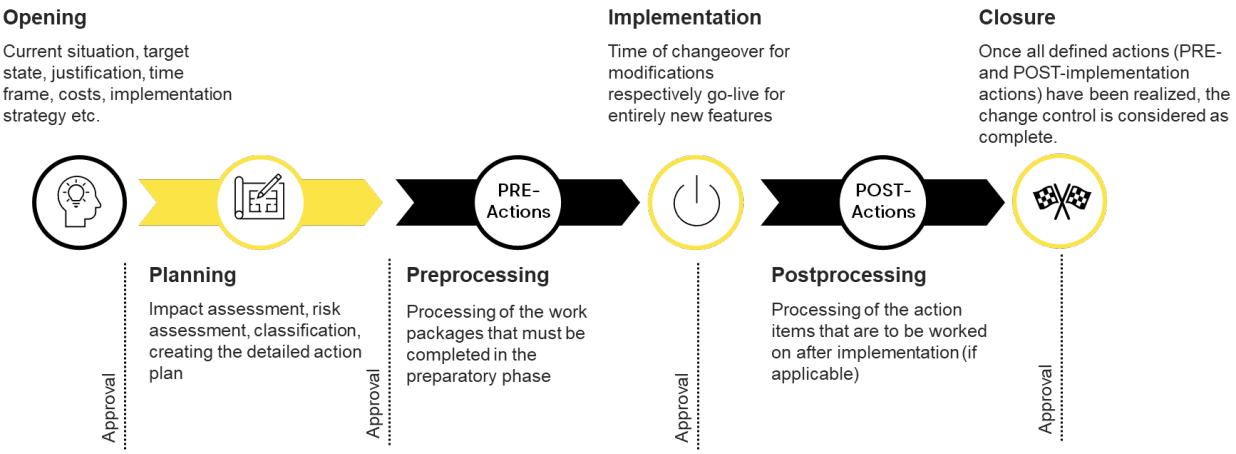

Figure 4 : Change control process flow

4.3.1 Opening change control

All employees should be able to submit a change request. Ideally, there should be an IT tool in which the following information can be directly entered:

Current situation: Description of the actual status. How is the process/service currently carried out? Which resources/systems are used? Who is responsible for which step? Who is involved?

Target stat: Description of the desired status. How should the process/service be carried out in future? With which resources/systems, with which responsibilities?

Reason/justification: List of the reason(s) that explain the benefits or necessity of the change (e.g. regulatory necessity/compliance, findings from internal/external audits, increased automation/efficiency, simplification and/or harmonisation of processes, cost savings, capacity expansion, etc.).

Costs/time frame: Cost estimate and time frame in which the change can/must be implemented.

Implementation strategy: Information on the implementation of the change. Is it necessary to involve external service providers, or can the change be handled entirely internally? Are there any dependencies on other changes, projects, etc.? Is there a chronology to be observed? What work needs to be carried out after implementation?

4.3.2 Initial review

Submitted change requests should be reviewed by management and a representative of quality assurance for comprehensibility and completeness of information. Where necessary, additions/clarifications are added.

If the change management criteria are met and the benefits or necessity of implementation are recognised, initial approval is given and a person is appointed who is responsible for further planning and implementation.

If the change is not approved, the change control process is cancelled.

4.3.3 Impact and risk analysis

The person responsible for implementation, the management and a representative of the quality assurance shall independently evaluate the impact and risk of the planned change and record the results in writing.

Impact assessment
Evaluation of whether the change has an impact on

- IT systems and equipment
- Process landscape, individual processes
- Quality indicators
- Documentation
- Training requirements
- External service providers / stakeholders
- Regulatory aspects
- etc.

Risk assessment
Does implementation involve risks that could have a negative impact on the safety of organ donors or recipients, the effectiveness of organ and tissue transplantation, or the quality of the services provided? If so, what strategy must be followed to reduce the risks?

4.3.4 Classification

Based on the impact and risk analysis, the criticality of the change is determined by the QM/management. In practice, different classifications can be used for classification. Below is an example with the three classes "other", "significant" and "critical".

Other: A change that has no potential impact on the safety of organ donors or recipients or on the effectiveness of organ and tissue transplantation, but which represents an opportunity to optimise specified requirements or expectations for the services provided.

Example: Introduction of a document management system

Significant: A change that could indirectly affect the safety of organ donors or recipients or the effectiveness of organ and tissue transplantation.

Example: Replacement of LifePorts due to end of service life.

Critical: A change that has a direct impact on the safety of organ donors or organ recipients or the effectiveness of organ and tissue transplantation.

Example: Introduction of aNRP for DCD at hospital XYZ

The classification must be justified in writing.

4.3.5 Creating the action plan (change plan)

The person responsible for implementation defines all measures necessary to implement the change and creates individual work packages (change actions), each of which is scheduled and assigned to a person for processing.

Change actions are divided into PRE- and POST-implementation actions:

PRE-implementation actions are work packages that must be completed in the preparatory phase (e.g. the creation of specifications for a new IT system).

POST-implementation actions are work packages that must be completed after implementation (such as the controlled decommissioning and archiving of all data from an IT system after the successor solution has been put into operation). Depending on the type of change, there may be only PRE actions or both PRE and POST actions.

As a general rule, a corresponding action must be defined for all issues for which an impact has been identified in accordance with Chapter4.3.3 .

The entirety of all defined work packages (PRE- and POST-implementation actions) constitutes the action plan (change plan).

4.3.6 Approval of the action plan

Once the detailed action plan (=change plan) is in place, it is reviewed by management and the QM department/responsible. If necessary, revisions are requested. If the plan is accepted, the green light is given to start processing the defined work packages.

4.3.7 Implementation of the actions

The individual work packages (change actions) are processed as planned. Once a work package has been implemented, this is documented accordingly and reported back to management/the QM department/responsible.

4.3.8 Approval of the implementation of the change actions

Once all PRE-implementation actions have been completed, approval is granted by management and quality department/responsible. The change control is then considered implemented. This means that the new procedure is now officially in place (e.g. from now on, withdrawals from DCD-donations are made under aNRP, and quick withdrawals are no longer practised).

4.3.9 Finalization

If there are still work packages defined that can/should only be implemented after implementation (post-implementation actions), these must be completed accordingly. Once all defined actions (pre- and post-implementation actions) have been completed, the change control is considered as closed

4.4 Templates

Full process description including template available on request (cndo@swisstransplant.org).

5.0
Deviation management

5.1 Definition

Incidents, unforeseen events and deviations from established procedures can have an impact on the safety of donors/recipients or on the effectiveness of organ transplantation, as well as hampering cooperation between the parties involved.

All such occurrences (hereinafter referred to as "deviations") must therefore be reported to enable systematic review [EDQM Organ Guide [4]; Section 18.5.3.4.). The focus of the review is not on assigning blame, but on identifying deficiencies/gaps/ambiguities in the processes along the organ donation chain. The goals are to identify the root cause through a documented investigation, to eliminate the deficiencies through appropriate corrective measures and to reduce the risk of recurrence.

Depending on the scope of a deviation, various reporting systems are available:

- Internal hospital deviation system: For deviations in organ donation processes that only affect internal hospital procedures and have no impact on actors at other locations.

  Example: Failure of the operating theatre reservation system at Hospital XY, manual booking process, no delay in the planned surgery time.

- SLIDS-CIRS: For deviations in organ donation processes that affect stakeholders at other locations or stakeholders with different areas of responsibility (such as donation coordination, transplant coordination, procurement and transplant teams, Swisstransplant, AAA, etc.). SLIDS-CIRS is operated and maintained by Swisstransplant.

  Example: Significant delay in unaccompanied organ transport

- Vigilance reporting system: As a result of the partial revision of the Transplantation Act, an IT platform developed by the FOPH with mandatory reporting of serious adverse events will be introduced in 2027. A serious adverse occurrence (SAO) is the umbrella term for serious adverse events (SAE) and serious adverse reactions (SAR). Cases currently still recorded in SLIDS-CIRS in which a donated organ or a recipient was seriously harmed or could have been harmed will in future be processed in a separate vigilance reporting platform (see also chapter1.2).

  Example: Transmission of infectious diseases from donor to recipient

The following example of a process provides a structured and time-bound approach to reporting a deviation, documenting the investigation of the cause and assessing the (potential) impact of the deviation on the safety of donors/recipients, the effectiveness of organ transplantation or the requirements/expectations of the services provided. Furthermore, corrective and preventive measures are defined as part of the deviation process so that the problem is resolved and a recurrence is avoided.

5.2 Responsibilities

Reporting person: If an employee encounters a (potential) deviation, they are obliged to report it.

Person responsible for investigation: Responsible for documenting and processing the deviation.

Management: Collaboration in the investigation, reporting to executive management, provision of resources.

Quality Management (QM) department/responsible: Coordination of the investigation, editorial support, follow-up on measures.

Other participants: Where necessary and appropriate, additional expertise is requested for the root cause analysis (e.g. medical professionals, external stakeholders, etc.).

5.3 Process flow

The handling of a deviation is divided into several logical phases. These are listed below as examples.

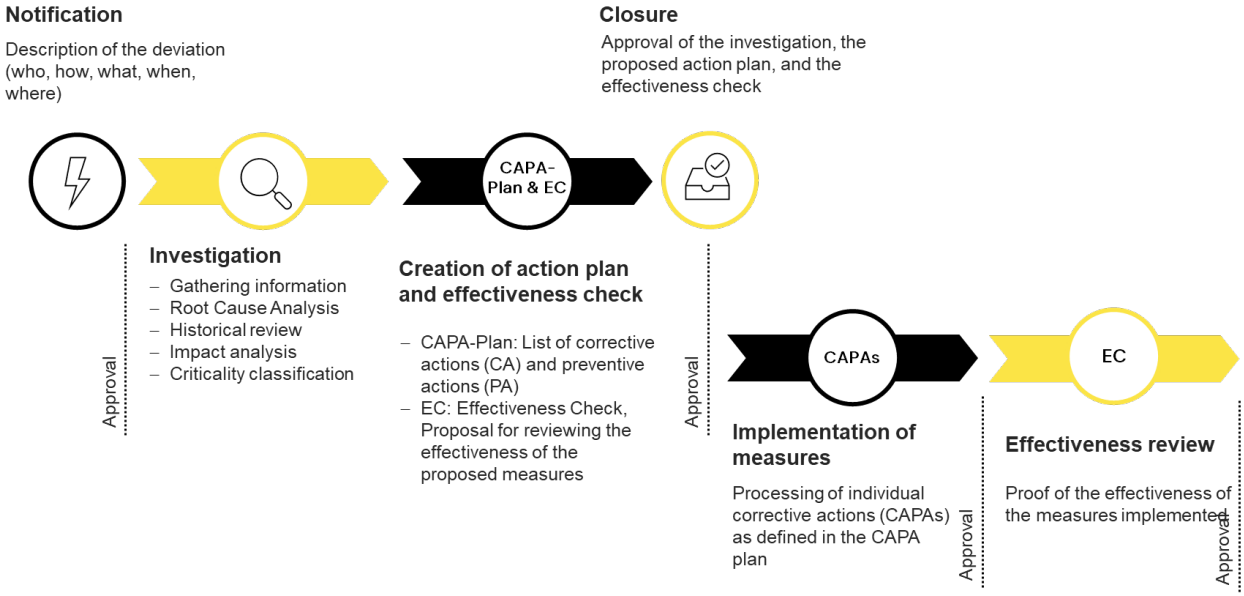

Figure5 : Process flow for deviations

5.3.1 Reporting a deviation

If a (potential) deviation is detected, it must be reported within a certain period of time (e.g. within 3 working days). Ideally, the report should be made directly in a designated IT tool. At a minimum, the following information should be recorded:

- Title of the deviation
- When did the deviation occur (if known)?
- When was the deviation discovered?
- Where did the deviation occur (physical location and/or process)?
- Which process/specification was deviated from?
- Who was involved in the process that led to the deviation?
- Were immediate measures taken?

5.3.2 Reviewing the notification

Once the deviation has been reported, the management and the QM department/responsible review the notification within a specified period (e.g. 3 working days). They check whether the information is complete and whether the event described meets the criteria for a deviation. If this is the case, the management appoints a person responsible for leading the investigating.

5.3.3 Investigation and root cause analysis

The deviation must be investigated systematically, taking into account all necessary information. Considering the varying degrees of complexity, a wide range of investigation techniques can be selected and combined:

- Conducting interviews/surveys
- Review/verification of documents and records
- Inspecting equipment and facilities
- Observation of processes
- Performing tests or simulations

Once all the necessary background information has been gathered, the root cause and any contributing factors are identified and documented. In addition to the **6M analysis** listed below, other tools such as the 5 Whys method or the Ishikawa diagram can also be used.

Method

- Work step not described in any specification document/process
- Inadequate work allocation
- Specification documentation/process inadequate
- Process/specifications not implemented correctly
- Employee not sufficiently trained on guidelines/procedures
- Other

Machine

- Defective machine/equipment
- Error in automation/IT system
- Maintenance/calibration not performed/insufficient
- Limited functionality
- Other

Measurement

- Insufficient measurement parameters (precision, accuracy, measuring range, etc.)
- Insufficient sample volume
- Error in sampling
- Incorrect value read out/recorded
- Other

Material

- No specification for the material/component
- Specification of material/component inadequate
- Material/component defective
- Other

Mother Nature (environment)

- Workplace design/environment not optimal
- Workload
- Interruption in public utilities (electricity, water, telecommunications, etc.)
- Other

Manpower

- Inattentiveness
- Incorrect decision
- Deliberate non-compliance with processes/guidelines
- Other

5.3.4 Historical review

To evaluate whether a deviation is recurring, a review of previous deviations should be conducted. Starting with the date on which the deviation was opened, the following time frame for the review is specified, for example:

- 3 months for daily tasks
- 6 months for weekly tasks
- 1 year for monthly tasks
- 2 years for quarterly tasks
- 5 years for annual tasks

To further narrow down the selection and determine whether it is a recurring deviation, the type of event and its root cause are compared with the current deviation.

If a recurring deviation is identified, the corrective/preventive actions (CAPAs) defined at the time and any existing effectiveness tests are critically reviewed and evaluated with regard to necessary adjustments.

5.3.5 Impact of the event

Identification of whether the deviation event had an impact (or potential impact) on the safety of the organ donor or recipient, the effectiveness of the organ and tissue transplantation and/or the quality of the services provided. If necessary, an additional medical assessment of the impact of the deviation by a medical professional may be requested.

If reports have been made to authorities and partners as a result of the deviation, these are also listed in this chapter.

5.3.6 Classification of criticality

Based on the historical review and the impact of the event, the criticality of the deviation is classified as "Minor", "Major" or "Critical". The classification must be justified in writing. Depending on the type of event, in addition to the "organ or tissue quality" level of consideration, other levels such as "impact on cooperation with stakeholders" or "financial damage" must also be taken into account (see also**Figure6**).

Minor: An incident or problem that had no potential impact on the safety of the organ donor or recipient or the effectiveness of the organ and tissue transplantation, but which constitutes a failure to comply with or meet specified requirements or expectations for < services provided.

Example: Internal hospital provision of outdated versions of controlled documents for organ and tissue donation.

Major: An incident or problem that had a potential impact on the safety of organ donors or recipients or the effectiveness of organ and tissue transplantation. Control over the next steps was still maintained, and the further course of action could be adjusted/controlled accordingly. This category also includes incidents that constitute a violation of legal principles or contractually agreed services, as well as incidents that could lead to financial losses or damage to reputation.

Example: Subsequent discovery that the contraindications for corneal procurement were not fully checked. The eye bank was informed in good time (before the preparation was released).

Critical: An incident or problem that had a direct impact on the safety of the organ donor or recipient or the effectiveness of the organ and tissue transplantation, whereby the further course of events could no longer be controlled. Or a serious breach of legal obligations and contractual content, which could lead to legal proceedings and/or significant financial losses or significant damage to reputation.

Examples:
- *Accidental destruction of donor files before the expiry of the statutory retention period of 20 years.*
- *Improper use of a LifePort kidney perfusion machine, resulting in the loss of the organ.*

Classification in the event of repeated deviations: If this is the third repetition of a deviation with a criticality rating of "Minor" and the CAPAs defined at the time have not been effective, the new deviation is to be classified as "Major". The same applies to a third recurrence of a deviation classified as "Major", which is upgraded to "Critical" accordingly.

5.3.7 Creation of an action plan (CAPA plan)

Based on the root cause analysis, a plan of action must be drawn up to address the deficiencies/non-conformities. The individual measures are referred to as CAPAs (Corrective And Preventive Actions).

Corrective actions (CA) are intended to remedy the identified deficiencies/non-conformities and prevent the same problem from recurring.

Preventive actions (PA) are intended to avoid similar deficiencies/non-conformities before they even arise. Preventive actions aim, among other things, to optimise process design, enhance monitoring, provide training, etc.

A deadline (date) and a responsible person/function must be defined for the completion of each individual measure.

5.3.8 Creation of an effectiveness check (EC)

An essential part of the CAPA process is to check the effectiveness of the measures taken after their implementation. To this end, a check is defined in advance to assess the effectiveness of the CAPAs (CAPAs are effective when the root cause and secondary problems have been resolved and appropriate controls are in place to prevent similar deviations).

A duration is defined for each effectiveness check (e.g. 6 months or 1 year). This starts from the point at which the action plan (i.e. all CAPAs) is implemented.

5.3.9 Approval of investigation and action plan

The finalised investigation report, including the action plan, is reviewed by management and the QM department/responsible and then formally approved. Once approved, the deviation is considered closed and the actions are now released for processing.

A deadline should be defined for the period from the opening to the closure of a deviation, e.g. 60 calendar days. If it becomes apparent that timely closure will not be possible, a written explanation must be submitted to the QM department/responsible with the following information:

- Status of the investigation to date
- Reason for the extension
- Impact analysis of the prolongation
- New due date

5.3.10 Implementation of measures

Processing of the CAPAs defined in the action plan within the specified time frame. If it becomes apparent that completion within the deadline will not be possible, a written explanation stating the reason for the extension and the new due date must be submitted to the QM department/responsible.

5.3.11 Final effectiveness check

Once the EC (Effectiveness Check) period has expired, a check is carried out to determine whether the measures implemented have prevented a recurrence of a similar deviation. If this is the case, the EC can be completed as "successful". If, on the other hand, a new deviation with the same root cause occurred during the EC period, further measures must be planned and implemented. In this case, the EC period is extended again by the initially defined period.

5.4 Templates

A complete process description including a template is available on request (cndo@swisstransplant.org).

6.0
Risk management

6.1 Definition

A complex process such as organ donation harbours potential weaknesses that must be investigated accordingly [EDQM Organ Guide [4]; section 18.5.3.5.). Risk analyses are used to identify potential sources of error throughout the entire process, assess them in terms of probability of occurrence, severity and detectability, and, where necessary, reduce them to an acceptable level through appropriate measures (such as CAPAs, see chapter 5.3.7). It is important to strike an appropriate balance between benefits, risks and resources.

> In addition to the purpose of "safety verification", risk analyses also serve to increase the reliability of procedures and generally create a better understanding of the functional relationships between actors, processes and materials.

6.2 Responsibilities

Management: Provision of resources, prioritisation of topics.

Quality Management (QM) department/responsible: Coordination of risk analyses, editorial support, follow-up on measures.

Internal employees: Assistance in developing deviating scenarios, classifying them and defining appropriate measures.

Internal/external stakeholders: Contribution of additional expertise with an "outside perspective".

6.3 Process flow

The process presented below is based on the principles of FMEA (Failure Mode and Effects Analysis). Originally developed by the US military in the 1950s, the system was subsequently applied and further developed in the aerospace industry, gained additional popularity in the automotive industry and is now a widely used tool that is applied in a wide variety of variations in all industries, including health care and life sciences. The FMEA variation below was designed by Swisstransplant for the specific needs of organ donation.

The use of other systems is also permitted, provided that a systematic approach is taken (e.g. PLDO "Cartographies des risques").

> Initially, risk analyses should be carried out on those topics/processes/sub-processes of organ donation that are considered to be the most "critical". Information on this can be found in the hospital's internal CIRS or in the SLIDS-CIRS, among other places.

Between 2020 and 2025, incident notifications in SLIDS in the "Procurement" category accounted for approximately 50% of all reported notifications. This compares, for example, to the "Donor Management" category which accounted for only approximately 10%. However, in the

latter category, it can be assumed that incidents of this type are primarily recorded in the hospital's internal CIRS (provided that no external stakeholders were affected).

The number of risk analyses carried out is to be continuously expanded. The long-term goal is to achieve complete coverage of the entire organ donation process chain.

As risks are often found at interfaces with internal/external stakeholders (such as contract laboratories, hospital pharmacies, medical device managers), these should be actively involved.

6.3.1 Risk identification

Scope: Definition of the scope of the risk analysis to be performed. It is possible to cover entire subject areas collectively or to consider individual work steps separately:

- Subject area (e.g. use of LifePort Kidney Transporter along the entire organ donation chain, i.e. from provision and use to cleaning and return)
- Process (e.g. transport)
- Sub-process (e.g. unaccompanied organ transport)
- Work step (e.g. entering HLA typing results)

Normal case (best case): Acquisition of knowledge/information about the process as intended (best case). Possible sources:

- Documentation (such as Swiss Donation Pathway, SOPs, work instructions, review of records)
- Surveys, group discussions
- Live demonstration

Exceptional case (bad case/worst case): Development of deviating scenarios (what might go wrong?)

The focus should be on critical quality attributes (e.g. pathogen-free allograft), critical material attributes (e.g. sterility of perfusion solutions) and critical process parameters (e.g. warm ischemia time).

6.3.2 Risk assessment

Severity: Assessment of the impact of the deviating scenario and classification into different classes, each of which is assigned a numerical value:

Catastrophic: 10 points/Critical: 8-9 points/Moderate: 5-7 points/Minimal: 3-4 points/Irrelevant: 1-2 points.

In addition to the impact on organ quality (e.g. imminent irreparable organ damage), other aspects must also be considered depending on the scenario, such as the impact on processes (e.g. significant delay in the procurement process), legal implications (e.g. incorrect allocation-relevant entries in SOAS) or financial consequences (e.g. financial loss due to incorrect use of LifePort kidney transporter kits).

Severity	Catastrophic	Critical	Moderate	Minimal	Irrelevant
Rating	**10**	**8-9**	**5-7**	**3-4**	**1-2**
Organ/Tissue Quality Impact	Failure of the procured organ/tissue in meeting internal or external specifications/regulations. Loss of graft.	Possible failure of the procured organ/tissue in meeting internal or external specifications/regulations. Potential loss of graft.	The procured organ/tissue is considerably affected but remains within internal or external specifications/regulations	The procured organ/tissue is slightly affected but remains within internal or external specifications/regulations	The procured organ/tissue is negligibly affected and remains within internal or external specifications/regulations
Process Impact	Process failure leading to donation/transplantation stoppage	Process failure resulting in a major impact on the donation/transplantation schedule	Process failure with a moderate impact on the donation/transplantation schedule	Process failure with a minor impact on the donation/transplantation schedule	No impact on donation/transplantation schedule
Regulatory Impact	The issue constitutes a breach of law and/or contracts that may lead to legal proceedings	The issue represents a direct deviation from an approved specification or regulatory commitment such that any organ/tissue procured under these conditions may be considered unsuitable for further use	The issue can conservatively be considered as a deviation from recognized best practices but does not represent a direct deviation from any regulation or guideline	The issue represents a potential deviation from internal requirements where the potential impact on quality is minimal	The issue has no impact on compliance.
Stakeholder Impact	The issue constitutes a direct breach of commitments made to stakeholders (like involved hospitals, donation networks, FOPH, health insurance companies, Swisstransplant, transport operators, etc.) that may lead to legal consequences or significant reputation damage	The issue represents a major deviation from comittements made to the stakeholders such that any interaction under these conditions may result in a strongly negative experience	The issue indicates a departure from the recognized best practices for stakeholder experience with a possible negative perception or minor inconvenience	The issue may lead to minimal inconvenience for the the stakeholder without enduring negative perception.	The issue has little to no discernible impact on stakeholder experience.
Financial impact	Loss of more than 30'000 CHF	Loss in between 10'000 and 30'000 CHF	Loss in between 5'000 and 10'000 CHF.	Loss in between 2'000 and 5'000 CHF	Less than 2'000 CHF

Figure6 : Classification table for severity

Probability of occurrence: Assessment of how likely the deviating scenario is and classification into different classes, each of which is assigned a numerical value:

Regular: 10/Probable: 8-9/Occasional: 5-7/Rare: 3-4/Unlikely: 1-2

Depending on the scenario, the probability of occurrence can only be evaluated qualitatively (subjective estimate). In other scenarios, however, a quantitative estimate or derivation from empirical values and key figures is possible (e.g. event X occurs in approximately 1 in 100 donors, or event Y occurs on average every two years).

Likelihood	Frequent	Probable	Occasional	Remote	Improbable
Rating	**10**	**8-9**	**5-7**	**3-4**	**1-2**
Qualitative	Highly likely to occur	Likely to occur	Possible to occur	Most likely will not occur	Highly unlikely to occur
Quantitative	~ 1 per 5 donor	~ 1 per 10 donors	~ 1 per 200 donors	~ 1 per 1000 donors	less than 1 per 1000 donors
Chronological	Less than 7 days	From 7 days to 30 days	From 30 days to 1 year	From 1 year to 5 years	Less than once per 5 years

Figure7 : Classification table for the probability of occurrence (frequency)

Detectability: Evaluation of whether suitable control mechanisms exist and how long it is likely to take to detect the error. Classification into different classes, each assigned a numerical value:

Very low detectability: 10/Low detectability: 8-9/Moderate detectability: 5-7/High detectability: 3-4/Continuous detectability: 1-2

Detectability	Very Low	Low	Moderate	High	Very High
Rating	**10**	**8-9**	**5-7**	**3-4**	**1-2**
Qualitative	No controls in place	Failure not easy to detect	Detection is delayed	Very like that the controls will detect the failure	The control will detect the failure almost in every instance
Quantitative	0-10%	more than 10 less than 30%	more than 30 less than 70%	more than 70 less than 90%	90-100%
Chronological	More than 30 days	From 7 days to 30 days	From 1 day to 7 days	From 6 to 24 hours	Less than 6 hours

Figure8 : Classification table for detectability

RPN (Risk Priority Number): Calculation of the risk priority number (multiplication of severity x probability of occurrence x detectability).

The calculated RPN value is used to classify events into several risk classes. Additional weighting is given to the severity. This is to take into account the fact that events with potentially critical outcomes must be mitigated by measures even if they have a low probability of occurrence and high detectability.

RPN		Severity				
From	To	Irrelevant	Minimal	Moderate	Critical	Catastrophic
400	1000	Not achievable	Moderate Impact	High Impact	High Impact	High Impact
101	399	Low Impact	Moderate Impact	Moderate Impact	High Impact	High Impact
51	100	Low Impact	Moderate Impact	Moderate Impact	Moderate Impact	High Impact
26	50	Low Impact	Low Impact	Low Impact	Moderate Impact	Moderate Impact
1	25	Low Impact	Low Impact	Low Impact	Low Impact	Moderate Impact

Figure9 : Table for criticality classification

6.3.3 Risk control

The classification into risk classes is used to determine whether measures need to be taken:

- High impact: Measures are absolutely necessary.
- Medium impact: Measures are recommended.
- Low impact: No action necessary.

Possible measures may include:

- Discontinuing the high-risk activity.
- Eliminate the source of risk.
- Changing the impact and/or frequency and/or detectability of the risk.
- Acceptance of a risk (for risks with a "medium impact").

Ideally, the implementation of the selected measures is controlled by means of CAPAs.

6.3.4 Risk monitoring

- The risk analyses performed are recorded as controlled documents and are subject to a standard periodic review (usually annually or in accordance with local SOPs, see chapter 3.3.1).
- In the event of deviations, incidents and change controls, the existing risk analyses must be reviewed in situ and revised where necessary.

6.4 Templates

A complete process description including a template is available on request (CNDO@Swis-stransplant.org).

7.0
Self-evaluations and audits

7.1 Definition

Self-evaluations and audits are essential aspects of the continuous improvement process (EDQM Organ Guide [4]; section 18.5.3.1.). Auditing serves to verify whether

- the (quality) management system is being applied correctly and effectively in practice
- all normative principles and internal/external requirements are being complied with
- the established procedures and processes still correspond to actual practice

The form of self-evaluation is flexible. Checklists are often used for this purpose. The following section primarily describes the internal audit process, although some elements of it can also be applied to self-evaluations.

7.2 Responsibilities

Quality Management (QM) department/responsible: Responsible for planning the audit programme (topics/focus areas, audit frequency) and its implementation (appointing/supporting the audit team, ensuring formal requirements are met, editorial support for the audit plan/audit report/action plan).

Audit team: Responsible for conducting the respective audits and producing the resulting documentation (audit plan/audit report). An audit team usually consists of a lead auditor (interaction with the audited bodies) and a co-auditor (in-situ documentation). The audit team may consist entirely of members of the QM department/responsible, or other persons with the necessary expertise/training may be called in (e.g. from the medical profession, the hospital's QM unit, etc.).

Audited unit: Team of employees with in-depth specialist knowledge of the respective audit topic. Answers questions from the audit team and provides insight into documents/processes/systems. Based on the audit report, the audited unit draws up an action plan in collaboration with management.

Management: Defines the topics/focus areas/frequency of the audits together with the QM department/responsible. Ensures that audits run smoothly in their organisational unit. Puts together the team for the audited unit. Evaluates the audit report and draws up the action plan together with the audited unit. In the event of divergent views on the findings, makes a decision on whether or not measures need to be taken.

7.3 Process flow

7.3.1 Audit preparation

The focus of the internal audit is determined in advance. Both general topics (compliance with QM processes) and area-specific fields of work (individual tasks in the donation process) should be taken into account.

General: Document management, process management, change management, deviation management, risk management, information and data security, etc.

Area-specific: Specialist tasks in the donation process in accordance with the organisational chart / quality manual / job description / process and document landscape.

In preparation, processes, documents and records are reviewed in order to gain an in-depth understanding of the functional relationships between actors, processes and materials. If not all relevant documents/documentation are already available/accessible, they can be requested when the audit plan is sent out.

7.3.2 Audit plan

The audit plan is sent to the audited entity in advance (with sufficient lead time). The audit plan contains general information (date/location, details of auditors and auditees) and a schedule/timeline with key topics. It is important to also schedule "auditor time". This gives the auditors the opportunity to take a break, review and update the documentation, discuss potential deficiencies and agree on how to further proceed.

Within the audit plan it is also possible to require documents/documentation to be provided in advance if the auditor team has only limited access.

The audit plan enables the audited entity to prepare adequately for the topics, provide the necessary documents and, if planned, organise tours or live demonstrations or inspections of materials/equipment. This avoids delays in the audit process.

7.3.3 Conducting the audit

- Introductory meeting: Welcome to those present, presentation of the scope and procedure of the audit.
- Auditing of the planned topics.
- Auditors time: Review of documentation, identification of deficiencies and their provisional classification.
- Final meeting: Feedback on the audit, the deficiencies identified and their provisional classification. Information about the next steps (receipt of audit report, submission of action plan, etc.).

7.3.4 Audit report

Within a specified period (e.g. one month after the audit has been carried out), the audit team submits a detailed report to the audited body and its management. This report contains:

- General information about the audit (such as date, participants, purpose, scope, legal and/or normative basis and internal regulations)
- Summary and general impression (organisation and responsibilities, quality management system, personnel, premises, etc.)

- Findings: Findings may relate to missing requirements (absence of processes and/or regulated documentation) as well as the inadequate implementation of existing requirements in practice.

  Not only are deficiencies that (potentially) affect the quality of the organ or tissue or the success of the transplant taken into account, but also those that (possibly) negatively impact cooperation with stakeholders or may have legal or financial consequences (see alsoFigure6).

  Findings are classified into categories according to their potential danger and risk. In practice, different classifications can be used for this purpose. Below is an example with three categories: "critical", "major" and "minor".

  - Critical: Deficiencies that could have a significant impact on the safety of donors/recipients or on the effectiveness of organ and tissue transplantation. Deficiencies that constitute a gross violation of legal principles or contractually agreed services. Deficiencies that could lead to considerable financial losses or damage to reputation.

    Example:

# / Title	C.01 / Expired LifePort Kidney Transporter Disposable Kit
Fundamentals	EDQM Organ Guide 9th edition, 18.5.3.8 Premises, equipment, materials and contractual arrangements Guideline on decentralised storage of medicinal products and medical devices Hospital Pharmacy ABC, Version 7.0, Chapter 1.2 Responsibilities
Comment	The accessories for the LifePort Kidney Transporters are stored in supply room 907.B. During the tour, an expired perfusion circuit kit was found (LKT200 Perfusion Circuit, lot number 9FFACC18, EXP 2021-06-24). This was neither stored separately nor marked accordingly (e.g. "Material expired, may only be used for training purposes").

  - Major: Deficiencies that may affect the safety of donors/recipients or the effectiveness of organ and tissue transplantation. Deficiencies that constitute a violation of legal requirements or contractually agreed services. Deficiencies that may lead to financial losses or damage to reputation.

    Example:

# / Title	M.07 / No valid export licence for homografts available
Legal basis	Transplantation law SR 810.21, Art. 25 Permit requirement for storage, import and export. Guideline on contract Management Hospital XYZ, Version 3.0, Chapter 7.2 Subcontractors
Comment	In the context of organ donation, human body parts are sent to the EHB in Brussels for the preparation of cardiovascular homograft. Export requires a corresponding licence from the FOPH, which is not available in this case.

  - Minor: Deficiencies with no potential impact on the safety of donors/recipients or on the effectiveness of organ and tissue transplantation, but which nevertheless constitute a deviation from internal and/or external requirements. This category often includes deficiencies based on inconsistencies in the implementation of requirements or a lack of traceability in the documentation.

    Example:

# / Title	m.12 / Periodic review of documents is not ensured
Fundamentals	EDQM Organ Guide 9th edition, 18.5.3.2. Documentation and registries SOP Document Management Hospital ABC, Version 3.0, Chapter 5.2. Document Control
Comment	During the audit, it was found that several documents were overdue for periodic review (process description for donor detection in the emergency room v2.0, overdue since 27 August 2023 / Checklist for the discussion with relatives v7.0, overdue since 15 March 2024):

- Recommendations: Unlike findings, recommendations are not based on non-compliance with requirements but represent an opportunity to improve efficiency.
- Conclusions (fully compliant, substantially compliant, not in compliance), date of submission of action plan, acknowledgement.

7.3.5 Action plan

The audited unit works with the management to draw up an action plan in response to the audit report. For each finding, the action plan describes what improvements will be made, when they will be implemented and who is responsible. Ideally, the proposed improvements are entered as CAPA in a suitable IT tool (see also chapter 5.3.7). If no such tool is available, this can also be done in a separate document.

7.3.6 Confirmation of action plan

The audit team reviews the action plan and then formally approves it. Once approved, the audit is considered complete and the measures are now ready for implementation.

7.3.7 Implementation of measures

Management coordinates the implementation of the measures together with the persons responsible as defined in the action plan. The status of implementation will be reviewed at the latest during the next audit.

8.0
Quality indicators & SwissPOD

8.1 Definition

A quality indicator (QI) is a quantitative tool for monitoring and evaluating the quality of structures (organisation, resources), processes and results. Its use allows both success to be measured and potential problem areas to be identified (EDQM Organ Guide [4]; section 18.5.2.2.).

The values collected by QI may fall within or outside a reference range or exceed or fall below a reference value. The term "key figure" is often used synonymously with the term "quality indicator".

8.2 Defining quality indicators

The process of defining quality indicators involves several steps [10]. These steps are summarised below:

1. Identification of relevant quality aspects
   - Determination of critical points in the organ donation process that need to be monitored.
   - Identification of all possible metrics.
2. Defining indicators
   - Develop specific indicators that measure these specific quality aspects.
   - Target values: Defining reference values or reference ranges.
3. Data collection
   - Measure and collect data on the defined indicators.
4. Analysis and reporting
   - Analyse the data (where appropriate, use statistical methods to identify trends and anomalies).
   - Present the findings in the form of a report.
   - Discussion of the report with the relevant responsible persons and decision-makers.
5. Feedback and improvement:
   - Define and implement improvement measures based on the report and discussion.
6. Review the effectiveness of the measures
   - In the following reporting period, the effectiveness of the implemented measures is evaluated (using the indicators). Plan further measures depending on the results.

8.3 Requirements for quality indicators

Quality indicators are themselves subject to quality criteria. According to the RUMBA rule [11], QIs should meet the following requirements:

- Relevant – important for a selected problem area
- Understandable – comprehensible to service providers and patients
- Measurable – measurable with a high degree of reliability and accuracy
- Behaviourable – influenceable through action and behavioural changes
- Achievable and feasible – realistically achievable and practicable

Extensive examples of quality indicators in organ donation were developed in the EU project ODEQUS [12].

8.4 SwissPOD

In Switzerland, quality indicators for the organ donation process are calculated by the **Swiss** monitoring of **po**tential **d**onors (SwissPOD) tool, both on national level and at the level of the individual organ donation networks. A report is published every six months.

What is SwissPOD?

Since 2009, Swisstransplant and the CNDO have been commissioned by the Swiss Conference of Cantonal Health Directors (CMPH) to coordinate the cantons' tasks at national level as specified in Article 45 of the Transplantation Ordinance and to promote cooperation between the networks. The mandate includes, among other things, quality control of the organ and tissue donation process and the evaluation of measures implemented. One tool used to fulfil this mandate is the SwissPOD online application, which all Swiss hospitals with an intensive care unit recognised by the Swiss Society of Intensive Care Medicine (SGI) use to record information on all deaths in intensive care units and emergency departments from internal hospital patient records.

The data entered into SwissPOD is analysed to calculate quality indicators for the following purposes:

- **Improvement of donation processes:** How many organ donations from deceased persons would be possible, where is the potential not being exploited and for what reasons? The SwissPOD indicators provide information on how well the donation processes are implemented in the various networks and hospitals. By identifying individual areas for improvement, tailored measures can be taken to specifically improve structures and processes in individual networks or hospitals, thereby increasing the number of organ donations realised.
- **Awareness and self-monitoring:** The systematic recording of deaths with a view to possible organ and tissue donation, as well as regular reporting of SwissPOD indicators, raises awareness of the issue among medical professionals involved in end-of-life care and encourages networks and hospitals to evaluate themselves and take responsibility for organ and tissue donation. In addition to critically examining their own performance, this also serves as proof of what has already been achieved.
- **Comparability and mutual learning:** The SwissPOD indicators enable comparisons between networks and hospitals for selected periods. They form the basis for discussions and the exchange of best practices on specific aspects of the donation process (such as discussions with relatives) and thus support joint, mutual development throughout Switzerland.

- **Monitoring and control**: SwissPOD indicators help to ensure that decisions are made on the basis of evidence rather than politics or intuition. They support the allocation of resources in line with needs and make it easier to review the effectiveness of measures implemented.

What data is collected in SwissPOD?

In addition to basic patient characteristics (age, gender, place of residence, hospital) and information on hospital admission, medical data such as diagnoses, causes of death, contraindications for organ and tissue donation, and signs of severe brain damage are recorded. Detailed information is also requested on the identification and evaluation of donors, any withdrawal of treatment, discussions with relatives and consent/refusal to donate.

The questionnaires vary in type and scope depending on whether or not a donation took place in the event of death, whether it was a DBD or DCD-Donation, and whether only organs, only tissue, or organs and tissue were donated.

- Questionnaires on deaths involving organ donation are deliberately kept short, as the donation processes were successfully completed in these cases (non-utilised donors [NUT] are also considered deaths involving organ donation).
- Questionnaires on deaths without organ donation are more extensive, as they are relevant for estimating donation potential and for improvement measures.

How is the data from SwissPOD evaluated?

Swisstransplant publishes the information obtained from SwissPOD in a **biannual report.** This report shows all quality indicators for Switzerland as a whole and separately for all networks and transplant centres over a maximum of five consecutive years.

Half-yearly SwissPOD publication [13]
www.swisstransplant.org/de/organ-gewebespende/fakten-und-zahlen/swiss-pod-reporting

A **traffic light system** visualises the reference ranges of the indicators. The green range is defined as the target range to be aimed for in all indicators. Using the time series and the traffic light system, networks and hospitals can keep track of their development and work with Swisstransplant and the CNDO to develop measures for optimisation.

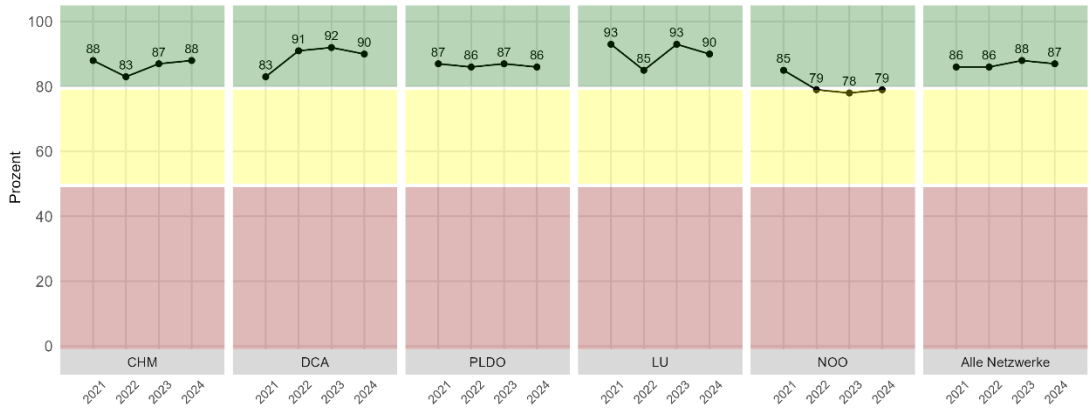

Figure10 : Quality indicator "Frequency of discussions with relatives" (approach rate) over time. This QI shows very good performance by almost all networks.

In addition to the traffic light system, the data entered is also visualised in form of a flow chart.

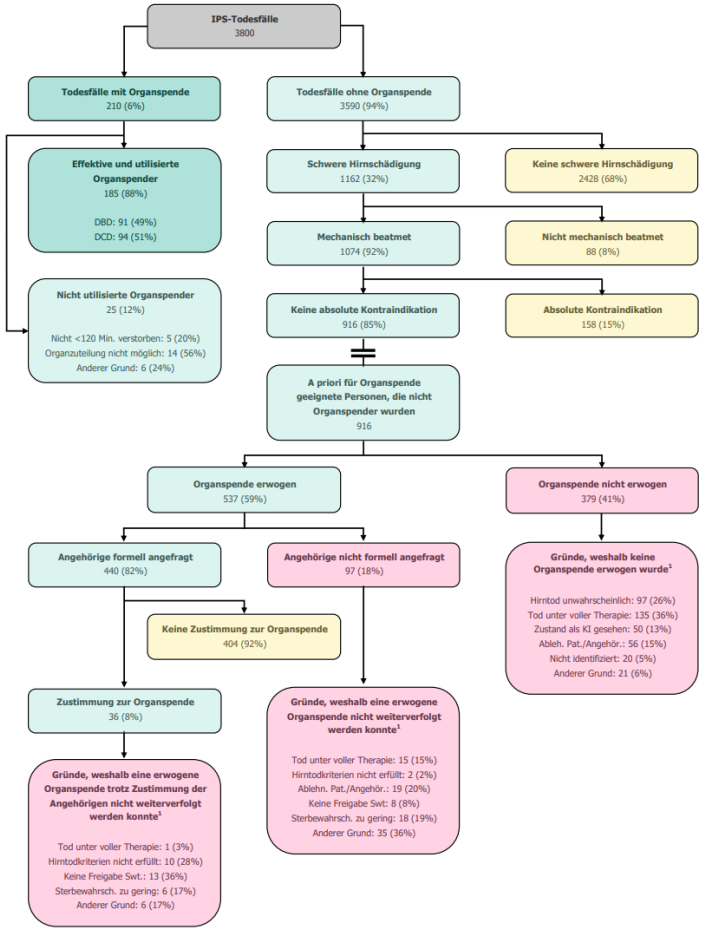

Figure11 : SwissPOD flow chart, whole of Switzerland, 2024.

Measured indicators

The SwissPOD indicators all relate to deaths in intensive care units. It is not possible to report the same indicators for emergency departments, as patients are identified as potential organ donors in the emergency department but are then transferred to the intensive care unit for further steps.

- Evaluation rate: The evaluation rate determines the proportion of potential donors who were evaluated or considered as organ donors.

$$\frac{\text{Anzahl Todesfälle, bei denen eine Organspende erwogen wurde}}{\text{Anzahl Todesfälle von a priori geeigneten Personen}} \times 100$$

- Approach rate: Determines the proportion of potential organ donors for whom a discussion with relatives took place. Discussions with relatives are all discussions for the purpose of formal decision-making with regard to organ donation.

$$\frac{\text{Anzahl Todesfälle mit Angehörigengespräch zur Organspende}}{\text{Anzahl Todesfälle, bei denen eine Organspende erwogen wurde}} \times 100$$

- Consent rate: The consent rate describes the number of consents to organ donation given during the discussions with relatives in relation to all discussions with relatives hold. Discussions with relatives are all discussions for formal decision-making with regard to organ donation.

$$\frac{\text{Anzahl Zustimmungen zur Organspende im Angehörigengespräch}}{\text{Anzahl Angehörigengespräche zur Organspende}} \times 100$$

- Organ donation rate: The organ donation rate indicates the number of deaths with organ donation in relation to all ICU deaths. All donors (utilised, effective and non-utilised) reported to Swisstransplant via the Swiss Organ Allocation System (SOAS) are taken into account.

$$\frac{\text{Anzahl Todesfälle mit Organspende}}{\text{Anzahl Todesfälle auf Intensivstation}} \times 100$$

- DBD realisation rate: Hospitals with neurological departments treat people with severe brain damage more often than hospitals that do not have a stroke unit. The DBD utilisation rate compares the number of DBD organ donors to the donation potential. This allows an assessment of how well a network or hospital is utilising its DBD donation potential. All donors reported to Swisstransplant via SOAS (utilised, effective and non-utilised) are taken into account for DBD organ donation.

$$\frac{\text{Anzahl Todesfälle mit DBD-Organspende}}{\text{Anzahl Todesfälle von a priori geeigneten Personen}} \times 100$$

- DCD realisation rate: The DCD realisation rate compares the number of DCD organ donors with the DCD potential. This allows a more accurate assessment of the actual DCD activity of a network or hospital. All donors reported to Swisstransplant via SOAS (utilised, effective and non-utilised) are taken into account for DCD-Donation. A DCD-Donation is only possible if the following three criteria are met: planned withdrawal of treatment, no contraindications, death within 120 minutes.

$$\frac{\text{Anzahl Todesfälle mit DCD-Organspende}}{\text{Anzahl Todesfälle mit DCD-Potenzial}} \times 100$$

8.5 Further indicators

Further indicators can be helpful for optimising operational activities within the hospitals and serve as basis for strategic decision-making at network level, such as

- Proportion of discussions with relatives in which a donation coordinator is present.
- Organ donation rejection rate depending on the presence or absence of a donation coordinator during the conversation with relatives.
- Percentage of corneas removed in relation to the number of eligible patients who have consented to donation.

The definition of further quality indicators is at the discretion of the local donation coordination management or network heads. Ideally, these should be developed and maintained by the medical professionals responsible for quality management in organ donation networks (Q-FOGS).

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Changes

Date	Version	Changes
February 2026	1.0	First edition

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