

Chapter 9

The Donor

Change record

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February 2020	B.F.J. Goudsmit	7.0	Standardized SAE/SAR reporting of micro-organisms has been added.
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The Eurotransplant Manual contains the rules and regulations for the implementation and specification of national legislation and national guidelines for waiting list management, organ procurement and allocation. It has been prepared with the best of knowledge and the utmost care. In case of discrepancies between the content of this manual and national binding provisions, the following applies:

- Insofar, as provisions about the acceptance of organ recipients to the waiting list are concerned, this manual has only an informative character. Only the national provisions which are applicable for the transplant centers are relevant and legally binding.
- For the allocation of organs only the national provisions are legally binding. The display of the allocation provisions in this Manual are based on these legally binding national provisions. As far as necessary, they have been specified by Eurotransplant in this Manual. Deviations from such specifying Eurotransplant provisions cannot be considered as a breach of the national provisions as long as the latter are not violated. Eurotransplant cannot be held liable for a potentially wrongful description in this Manual of procedures, in connection with the organ allocation, as long as the actual allocation follows national provisions.

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9.1 Introduction

The aim of this chapter of the Eurotransplant Manual, like the aim of the EU Directive 2010/45/EU⁽¹⁾, is to ensure standards of quality and safety for human organs intended for transplantation.

As donor organs are scarce, a detailed donor evaluation and state of the art donor management is of the utmost importance. Both components will improve the efficacy and efficiency of organ allocation and thereby facilitate maximum utilization of donor organs.

The donation procedure (donor detection up to organ procurement) is extensive. A standard set of minimal donor data has been developed in order to facilitate this procedure.

When a donor is reported, this mandatory data should be transferred immediately to the Eurotransplant duty desk. Besides the minimal dataset, additional data can be provided. These data could be relevant for optimal organ allocation.

Data must be submitted through DSO.isys (in case of German donor) or through DPA (The Netherlands, Belgium (2007), Austria (2008) and Luxembourg (2009)). Croatia and Slovenia (2008) have started with their own system, which is electronical and compatible with the ENIS system.. Hungary is a Eurotransplant member since 2013 and also uses an ENIS compatible system.

This chapter will provide *general* guidelines on donor management and organ procurement.

The following will be adhered concerning this manual⁽²⁾:

1. Each change or addition to the protocols described in Chapter 9 'The Donor' of the ET Manual must evaluate the possible risks and repercussion on the procurement and quality of other organs.
2. If there is a possible repercussion, this must be discussed in the respective ET Advisory Committees.
3. Thereafter feedback must be given to the organ procurement teams / OPO's about the discussion in the respective ET Advisory Committees.

In the previous version of this chapter a lengthy description was included on procurement procedures in the subsections of Donor Management and Procurement Guidelines. These procedures are the responsibility of the national competent authorities of the ET member states according to the EU Directive. Aspects of procurement that have been specifically agreed upon by all member states in the organ advisory committees will still be documented in these chapter subsections.

1) Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

2) P-OPC01.12. accepted 14.05.2012

9.1.1 Definitions with regard to organ donation

9.1.1.1 *Reported donor*

A person for whom consent has been given for organ donation and that is reported to the Eurotransplant duty desk..

9.1.1.2 *Actual donor*

Consented eligible donor:

1. In whom an operative incision was made with the intent of organ procurement for the purpose of transplantation
2. From whom at least one organ was procured for the purpose of transplantation

9.1.1.3 *Reported actual deceased donor*

An actual donor from whom at least one organ was transplanted after brain death and/or cardiac arrest (CA).

9.1.1.4 *Donation after brain death (DBD)*

A person diagnosed with brain dead according to current national regulations and laws on transplantation.

9.1.1.5 *Donation after circulatory death (DCD)*

A person of whom death is confirmed using circulatory criteria according to the respective national laws and regulations.

Please note: *Not all countries within Eurotransplant allow reporting DCD donors or accepting organs from a DCD donor. National regulations are applied accordingly in the allocation of the organs.*

Categories of DCD³⁾

Modified Maastricht Classification for Donation after Circulatory Death:

UNCONTROLLED	I	Dead on arrival	Includes victims of a sudden death, whether traumatic or not, occurring out or in the hospital and who, for obvious reasons, have not been resuscitated.
	II	Unsuccessful resuscitation	Includes patients who suffer a CA and in whom CPR was unsuccessful. CA occurs out or in the hospital, being attended by health-care personnel with immediate initiation of CPR.
CONTROLLED	III	Awaiting cardiac arrest	Includes patients in whom withdrawal of life-sustaining therapies are applied, as agreed upon within the health-care team and with relatives or representatives of the patient.
	IV	Cardiac arrest while brain death	Donors who suffer from a cardiac arrest after the determination of brain death
	V	Euthanasia	Includes patients who are granted access to medically-assisted circulatory death.

Currently the ENIS system includes category V (euthanasia) under category III.

9.1.1.6 *Definitions of (ischemic) times***Total warm Ischemic time (WIT)**

Total warm ischemic time is based on the **warm ischemic time** during procurement and transplantation. This time primarily depends on whether the donor is a DBD or a DCD donor.

The following definitions are used:

- **Acirculatory warm ischemic time in Donation after brain death (DBD):** the time from closing the arterial clamp until the start of the cold perfusion of the organ (0 to a few minutes);
- **Functional warm ischemic time in Donation after circulatory death (DCD):**
 - Controlled DCD donors:
The time from a Mean Arterial Pressure below 50 mmHg or an arterial saturation of <80% until the start of cold perfusion.
 - Uncontrolled DCD donors:
The functional warm ischemic time in uncontrolled DCD donors is defined as the time from stop resuscitation till start perfusion.
- **Acirculatory warm ischemic time in Donation after circulatory death (DCD):** the time from asystole or circulatory arrest until the start of cold perfusion of the organ.

3) Categories of donation after cardiocirculatory death. Kootstra G, Daemen J, Oomen A. Transplant Proceedings, Vol 27, No 5, 1995: 2893-2894. Adapted after OPC meeting December 2015

Please note: When referring to the “**warm ischemic time**” please specify to avoid difficulties in definitions.

Extraction time period: Clamp closed and/or time from start cold perfusion of the aorta until time of removal of the organ from the body of the donor.

Procurement time period: time between closing of the arterial clamp in the donor until putting the organ in the transport box.

Box time period: time between putting the organ in the transport box until the organ is out of the box.

Anastomosis time period: time between putting the organ in the body of the recipient until the moment of opening the arterial clamp.

Transport time period: time between departure of the organ from the donor hospital until the time of delivery of the organ at the transplantation hospital.

Transplant time: start of organ blood perfusion at the moment of unclamping (clamp open) in the recipient.

Total ischemic time: Time period between clamp closed in the donor and time of clamp open in the recipient.

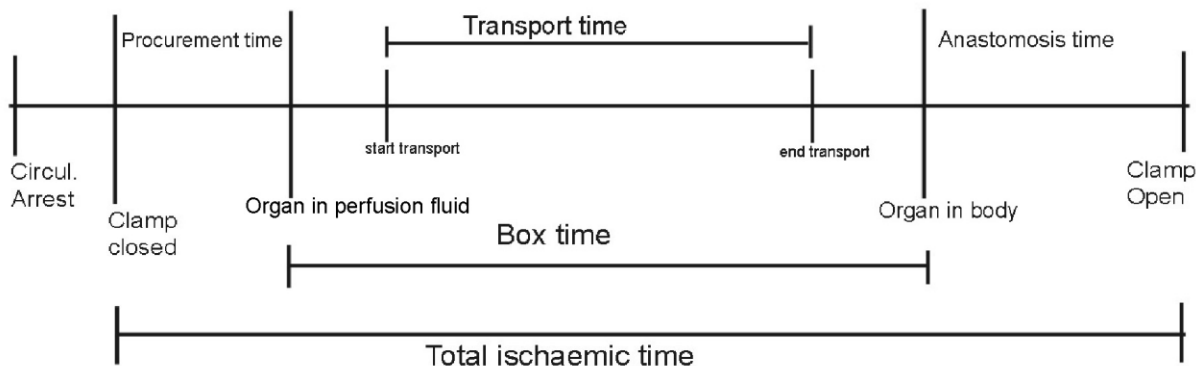


Figure 1

9.1.1.7 Multi organ donor (MOD)

A donor of whom at least two organs from different organ groups, e.g. heart and liver, are used for organ transplantation.

9.1.1.8 Single organ donor (SOD)

A donor of whom only one organ group, e.g. one lung or both lungs and no other organ, are used for organ transplantation.

9.1.1.9 *Kidney only donor*

A donor of whom at least one kidney and no non-renal organ(s) are used for organ transplantation.

9.1.1.10 *Non-kidney donor*

A donor reported of whom at least one non-renal organ and no kidney are used for organ transplantation.

9.1.1.11 *Living donor*

A living person who donates an organ for transplantation, such as a kidney or a segment of the lung, liver, pancreas or intestine. Living donors may be blood relatives, emotionally related individuals or altruistic donors.

National guidelines apply.

9.1.1.12 *Domino donor*

A recipient of a donor organ of whom an explanted organ is used for a consecutive second transplantation. A domino donor has a primary disease that allows the use of his/her explanted organ for a consecutive second transplant.

A domino donor can be considered a living donor if this is in accordance with current national guidelines and/or laws on transplantation.

9.1.2 Documentation of a donor procedure

Data on the donor is electronically transferred to the Eurotransplant systems by (Schnittstelle, DSO.isys or Donatie Procedure Applicatie, DPA-web service). All data entered automatically or by the Eurotransplant duty officers can be viewed during the organ offering process by using the web donor reports or via www.donordata.eu.

If, in rare cases, the data cannot be provided electronically via the official data exchange programs, the data must be submitted by fax or e-mail using standardized forms.

The following standard forms are required:

9.1.2.1 **ET Donor Information Form:** official documentation concerning organ donor data at time of reporting to Eurotransplant.

9.1.2.2 **Organ Report Forms:** forms per organ, official documentation concerning donor organs at time of procurement.

9.1.2.3 **Organ Quality Forms:** official documentation concerning donor organs at time of transplantation.

9.1.2.4 **Donor HLA Report:** official documentation concerning the donors HLA for the kidney match, used for other organs if relevant.

All forms are available at the members' site at www.eurotransplant.org under 'Forms'. If data is sent by fax or e-mail, the most current version of the official forms should be used and entered in the central computer by the Eurotransplant duty officers.

All reports must be in English.

- A. As of July 1 2011, exchange of donor information via the web-based application 'donordata.eu' (or similar web-based applications in use within the ET member countries) is mandatory.
- B. In exceptional cases, donor information is allowed to be provided in other ways (e.g. by fax/e-mail). Exceptional cases will only be considered as such if they are included in the 'donordata.eu exceptional case description'.
- C. A description of exceptional cases will be established prior to implementation of ROPC03.10 (e.g. technical calamities).

9.1.2.1 Donor Information Form (DIF): mandatory and optional data

Before organs will be offered for donation, a minimal set of mandatory donor information is required. The mandatory requirements are labeled on the DIF as (*). This information needs to be collected and send to the Eurotransplant duty desk. Every donor center and OPO must adhere to these minimal requirements.. .

Other relevant, but non-mandatory, data for donor evaluation should be added.

9.1.2.2 Organ Report Form

There are three organ reports available at www.eurotransplant.org:

- ET Thoracic organ report
- Liver/pancreasreport
- Kidneyreport

These forms should be filled out by the transplant coordinator (general donor data) and by the procuring surgeon (organ data). The organ quality can be evaluated at the time of procurement. At the end of procurement, the transplant coordinator has to verify the completeness of these forms.

Three copies of each organ report should be made.

- **One should included with the organ;**
- **One should be provided electronically or in exceptional cases be sent to the Eurotransplant Duty desk;**
- **One copy should be filed at the donor reporting center or organization.**

The data from these organ reports sent to the Eurotransplant Duty desk are entered into the central computer database for quality assurance and data analysis.

9.1.2.3 Organ quality form

There are five organ reports available at www.eurotransplant.org:

- Heart-lung quality form
- Liver quality form
- Pancreas quality form
- Pancreas for islet isolation quality form
- Kidney quality form

These forms include information on the quality of the organ, procurement and packaging. Findings on anatomic abnormalities, possible iatrogenic and packaing and/or transportation related injuries should be indicated.

For each procured organ, an organ quality form should be completed by the transplanting surgeon.

Three copies of each organ quality form should be made:

- **One copy should be sent to the head of the procurement center;**
- **One copy should be sent to the Eurotransplant Medical Administration;**
- **One copy should be filed at the transplant center.**

The data, provided to Eurotransplant, is entered into the central computer database for quality assurance and data analysis.

In case of any procurement or procedure related issues that threaten the suitability of an organ to be used for transplantation, the Eurotransplant Duty desk should be informed immediately.

For example, a change in relevant donor information should always be reported to Eurotransplant. Eurotransplant will immediately inform any accepting transplant center so they can decide whether the organ is still suitable and accepted for their selected patient. If not, the organ allocation will continue according to the allocation guidelines (see Chapter 3 manuals).

In all cases where an organ is threatened to be discarded or its quality is jeopardized, a copy of the organ quality form accompanied by a complaint letter indicating the cause of the possible/actual loss of the donor organ(s) for transplantation should be sent to the Eurotransplant Medical Staff and the OPO in charge of this procedure. This letter should be sent within one week from the initial transplantation date. These findings will be reported to the head of the involved transplant programs, the OPO and to the Medical Director of Eurotransplant. They will decide if further action is necessary and inform the Organ Procurement Committee if necessary.

9.1.2.4 Donor HLA Report

This report contains all the relevant information regarding blood group, HLA typing and tissue typing material.

9.2 Organizational aspects

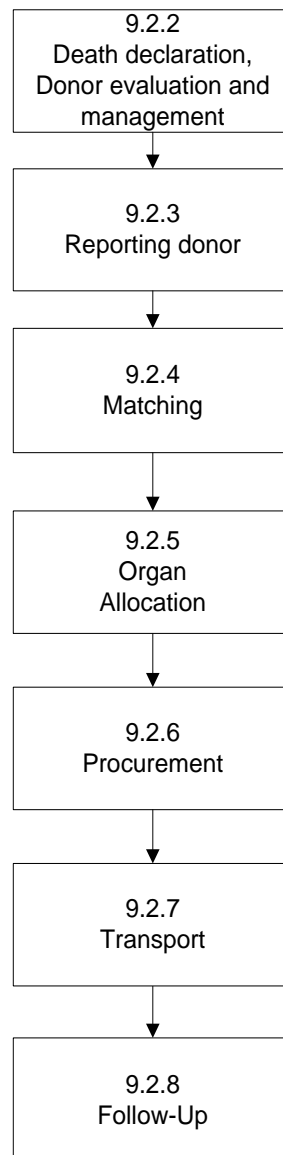
9.2.1 Introduction

Successful transplantation outcomes depend on a proper donor evaluation, donor management and donor reporting.

The following organ procurement flow chart gives a quick overview of the organizational aspects. Details will be discussed in the following sections.

9.2.1.1 Organ process from donor to transplant

Process from donor to transplant



9.2.2 Donor evaluation and management

9.2.2.1 *Death declaration of the donor*

The declaration of the death of the donor, the documentation and evaluation of the donor should be done according to the laws and regulations of each ET member state.

In addition to the death declaration, a consent for organ donation has to be obtained. In case of an unnatural death, legal authorities have to be contacted.

There is a special procedure in case of donation after circulatory death.

9.2.2.2 *Donor evaluation*

Complete donor evaluation and characterization is crucial for organ offering and accepting. It includes a detailed medical chart, and information on (relevant) medical and social history, a full physical examination and laboratory tests.

Organ related physicians of the donor center should be consulted to determine organ viability. They may also give support in establishing an optimal donor management plan.

Parallel to the donor evaluation, blood samples for AB0- and HLA- typing should be sent to the affiliated tissue-typing laboratory and virology/bacteriology tests should be performed. The minimum required donor data, according to the Eurotransplant guidelines (based on Annex part A, Directive 2010/45/EU of the European Parliament and the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation), should be collected (DIF).

9.2.2.3 *Donor management*

Donor management should start as soon as possible in order to facilitate a successful organ preservation, recovery and transplantation. .

Donor management is the responsibility of the doctor in charge, most of the time that would be the ICU doctor. We advise a donor management protocol at the ICU ward of each regional donor hospital.

9.2.3 Report to Eurotransplant

After the donor evaluation is completed and a donor management plan has been made, all necessary and relevant donor information (please see section 9.2.4.1) should be collected and transferred to Eurotransplant (See 9.1.2.)

At the time of reporting the donor to ET, the preferred time of organ procurement should be provided. A time frame of at least **6 hours** between reporting to the Eurotransplant duty desk and the planned start of procurement should be honored. The proposed time frame should take into account any possible difficulties during organ allocation or organizational problems from the side of the organ procurement

teams. In case the clinical condition of the donor or other relevant circumstances do not allow a 6 hour time frame, a shorter period for allocation must be discussed with the Eurotransplant duty office to ensure an optimal allocation.

Currently the procurement of the abdominal organs is performed by local procurement teams, while thoracic organs are procured by a procurement team from the accepting transplant center. In exceptional cases, if an (experienced) local organ procurement team could not be not available, The transplant coordinator should notify the Eurotransplant duty officer. The transplant centers can then be informed about this situation during the offering process. Arrangements can then be made for procurement with one of procurement teams of the accepting centers.

9.2.3.1 *Electronic donor reporting*

Currently, all Eurotransplant countries are using electrical systems to report a donor.

9.2.3.1.1 Isys - Schnittstelle

In Germany, the use of a national electronic data exchange program on organ donation "Isys" is mandatory for reporting a donor. Schnittstelle is the program that converts the data transfers this to the Eurotransplant Network Information system (ENIS).make the data available in ENIS / donordata.eu.

9.2.3.1.2 Donor Procedure Application – web service, (DPA-web service)

The Netherlands, Belgium, Luxembourg and Austria use a national electronic donor reporting system, the Donatie Procedure Applicatie or DPA.. Croatia, Hungary and Slovenia use a DPA compatible web service for electronically sending of donor information.

9.2.4 **Match relevant donor data**

Some of the donor data (the minimal donor data) will influence the composition of the match list and therefore have to be reported prior to the matching process. If not completed, standard allocation of the organs by using the ENIS system is not possible. The Eurotransplant matching system compares these donor data to recipient data.

The first step in the matching process is the selection of potential recipients based on the **donor blood group**, taking into account the rules set up by the different Organ Advisory Committees. The rules for the specific organs can be found in the respective chapters of this Manual.

9.2.4.1 *Minimal donor data for reporting a donor*

For reporting a donor to the Eurotransplant duty desk electronically, by fax or e-mail, a set of minimal donor data is mandatory (based on Annex part A, Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation).

9.2.4.2 Minimal data for matching

The list below entails the minimal data that must be reported before Eurotransplant duty desk can start the match or the allocation.

Data mandatory for match

Registration date	Hospital name
Center	Contact person
ABO	Contact tel nr.
RH	Death cause
Donor type (DBD, DCD)	Death date
Date of birth (DOB)	Admission date
Sex	Intensive care date
Height	Ventilation date
Weight	Cardiac arrest

Virology (HbsAg, HbcAb, HCV,HIV)⁵⁾

HLA (kidney donors), can be reported after the initial donor reporting.

9.2.4.3 Donor profiles and matching

The next step in creating the match list. Is filtering all recipients based on their center- and recipient-specific 'donor profiles' entered into ENIS. In this 'donor profile' several organ specific items (see below) can be entered. Only the recipients with a 'donor profile' that fulfills the donor data will appear on the match.

Note: Every change in the following donor match criteria will have an influence on the match on recipientlevel and/or on the whole match.

Match criteria for all organs:

- ABO-blood group
- Age
- Virology -HBsAg, HBcAb, HCVAAb
- Domino Donor
- Sepsis;
- Meningitis
- Malignant tumor
- IV-drug Abuse

For definitions of sepsis, meningitis, IV- drug abuse and malignant tumor, please see section 9.2.4.3.1.

Match criteria specific for heart:

- Height in combination with gender
- Virology - CMV IgG

Match criteria specific for lung:

- Total lung capacity (TLC) (combination of age, gender and height)
- Virology - CMV IgG
- Donation after cardiocirculatory death

5) Has to be known before transplantation, but preferable at time of reporting the donor

- Euthanasia donor

Match criteria specific for liver:

If the donor is considered to be a 'marginal donor' only the recipients with 'marginal donor: Yes' in their profile will appear on the liver match.

- Criteria marginal liver donor: one or more of the following points:
 - Donor age > 65 years
 - ICU stay with ventilation > 7 days
 - BMI >30
 - Steatotic liver > 40%
 - Serum sodium > 165 mmol/l
 - SGPT > 105 U/l
 - SGOT > 90 U/l
 - Serum bilirubine > 3 mg/dl
- Donation after cardiocirculatory death
- Euthanasia donor

Cut-off point to define a pediatric donor: donor weight < 46 kg vs. ≥ 46 kg

The allocation algorithm for pediatric donors (<46 kg): pediatric patients (<46 kg) are listed above the adult patients (≥ 46 kg) in the same urgency code group.

Match criteria specific for pancreas:

- Donation after cardiocirculatory death
- Euthanasia donor

Donor Cut-off point: pancreata fulfilling one of the following criteria:

- donor age > 50 (The Netherlands: >60)
- and/or BMI ≥ 30

will be allocated for pancreas islets transplantation only instead of vascularized organ transplantation.

German donors are excluded to this rule since islets specific allocation is not allowed in Germany and a vascularized pancreas matchlist is generated.

SU and ACO recipients who need a vascularized pancreas will still appear in the highest tier of pancreas islet matches.

An pancreas islets match can be forced for an organ that would be suitable for vascularized allocation. This should however be reported to the Eurotransplant duty desk at the time of reporting the donor.

Match criteria specific for kidney:

- Kidney en bloc (≤ 5 years) (mandatory < 2 years, advised ≥2 years and ≤ 5 years)
- Human Leukocyte Antigen (HLA) Mismatch
- Donation after circulatory death
- Euthanasia donor

Cut off point: donor age ≥ 65 years will be matched via ESP match instead of ETKAS match.

9.2.4.3.1 Definitions of sepsis, meningitis, IV-drug abuse and malignant tumor

9.2.4.3.1.1 IV-drug abuse

Yes	= intravenous drug abuse within 3 months before donor registration
Unknown	= no certainty of IV drug abuse within 3 months before donor registration
No	= certainty of no IV drug abuse within 3 months before donor registration

9.2.4.3.1.2 Malignancy

Yes	= every known malignancy in the previous history
No evidence	= no known history of malignancy in the previous history

In case a 'yes' for malignancy is entered, a specification on the malignancy should be given in the comment.

9.2.4.3.1.3 Sepsis

Yes	= positive blood culture with clinical symptoms
Unknown	= no certainty on sepsis status
No	= no clinical symptoms or any evidence of sepsis

In case a 'Yes' for sepsis is entered, a specification on the sepsis should be given in the comment.

9.2.4.3.1.4 Meningitis

There is no definition on meningitis, only the possibility to enter **Yes/No/Unknown**.
In case a 'Yes' for meningitis is entered, a specification on the meningitis should be given in the comment.

9.2.4.4 Donor data needed for allocation/decision per organ

In order to allow an adequate evaluation of the offered donor organs, additional organ specific data should be made available prior to offering the organ to the transplant centers.

Heart

- ECG
- Ultrasound

Lung

- Blood gas (any)
- Chest X-ray (recommended)

Liver

- Sodium (Na⁺)
- SGOT or SGPT
- Bilirubin
- Gamma GT

Pancreas

- Amylase or lipase

Kidney

- Creatinine or Urea
- Diuresis last hour

9.2.4.5 Donation after circulatory death (DCD)

In the Netherlands, Belgium, Luxembourg, Austria and Slovenia Donation after circulatory death (DCD) is allowed based on ethical and legal grounds.. Organs of DCD donors will only be offered to patients registered at a center in one the countries allowing DCD.

There are some specific rules for reporting organs from DCD-donors:

- Permission for donation must be given;
- In Croatia, Germany and Hungary donation, allocation, procurement and transplantation of DCD-organs are not allowed (national law and/or ethically). Therefore DCD-organs are not offered to recipients or transplant centers in these countries;
- DCD after euthanasia is reported as DCD V (since 2017) and documented as euthanasia –yes. Organs of these donors will not be offered to Austrian transplant centers.
- In Belgium, Netherlands and Austria, matching may take place at the moment the donor is reported and for kidneys as the HLA is known.

For further allocation rules please see the organ specific chapters of the Eurotransplant Manual.

9.2.4.6 Switch DCD to DBD(6)

If a donor type is switched from being a potential DCD to a DBD, Eurotransplant must restart the allocation process of organs that have not yet been accepted, offered or those that become available for new offers.

The incidence of these changes and the centers involved are monitored. The national competent authorities will be informed in case of a suspicion of manipulation.

9.2.4.7 Specific diseases of the donor**9.2.4.7.1 Rabies(7)**

The following guidelines are to be taken into account regarding transmission of the rabies virus through organ transplantation:

- Transmission of rabies through organ transplantation is a very rare event.
- Currently, no rapid blood or tissue tests are available which could reliably rule out the presence of rabies infection in brain dead organ donors.
- Rabies vaccination for potential organ recipients is not recommended.

9.2.4.7.2 Epstein Barr Virus(8)

- Epstein Barr test results might influence the post transplant treatment of a transplanted recipient.
- Testing for Epstein Barr Virus in potential donors is mandatory; it is allowed that

6) ROPC01.11, Accepted 23.01.2013

7) ROPC01.06, Accepted 30.05.2006, replaced by P-OPC03.13. in 2014

8) ROPC01.08, Accepted May 19, 2008

the test result is available after allocation.

- The test result should be forwarded to Eurotransplant. Eurotransplant will forward the information to the transplant centers.

9.2.4.7.3 LUES and toxoplasmosis⁽⁹⁾

- LUES and toxoplasmosis test results might influence the post-transplant treatment of a transplanted recipient.
- Testing for LUES and toxoplasmosis in potential donors is mandatory; it is allowed that test result is available within 72 hours after reporting the donor (not necessary to be known for allocational purposes). The test result should be forwarded to Eurotransplant. Eurotransplant will forward the information to the transplant centers.

9.2.4.7.4 HIV⁽¹⁰⁾

If a recipient is willing to accept an organ of HIV+ donors, this must be indicated in the donor profile of the recipient.

The following points should be respected as a policy of ET on HIV+ donors:

1. Proper and extensive categorization should be performed
2. Organs of HIV+ donors should be allocated to and accepted for HIV+ recipients
3. Transplantation of organs from HIV+ donors should take place in the framework of a standardized protocol
4. Procurement teams themselves should decide whether they are willing to procure the organs of HIV+ donors. If the local team is not willing to perform the procurement the transplant coordinator must inform ET as soon as possible in order to enable ET to inform the transplant center and to make arrangements for procurement by the transplant center.

HIV matching has not yet been implemented. This may be implemented with CORE.

9.2.4.7.5 Vague or dubious virology results

In case of a vague or dubious virology results.

For example:

- a. the lab technician cannot say whether the result is positive or negative
- b. in case a donor received several blood transfusions without the possibility to perform the test on a pre-transfusion blood sample

The organs of these donors should be matched and allocated assuming a positive virus result.

If possible, a second test should be performed. If this test result is negative and the organ has not been allocated yet, a new match should be made. The organ should be allocated according to the new match result.

9.2.5 Organ allocation

Directly after a donor is reported, the allocation of the available organs is initiated by the Eurotransplant duty officers. This is done in accordance to the rules developed by the organ advisory committees.

9) ROPC02.08. Accepted January 22. 2009

10) ROPC01.11 HIV. Accepted 25.01.2012

Organs will be offered in the following order:

Heart + lung → Heart → Lung → Liver → Intestine → Pancreas → Kidney

For each organ, except for the kidney, a primary offer as well as reserve offer is made. For the kidneys only a primary offer is made. The most recent information on the donor, can be found in the ENIS system and can be viewed in the donor report via internet (www.donordata.eu). To view the donor data, an account for the website and the ET donor number is necessary.

Any relevant received information that is not available in donordata will be sent by e-mail or fax to the transplant center(s).

More information about the allocation procedure is found in chapter 3 of the Eurotransplant Manual: Allocation.

9.2.6 Donor operating procedure

9.2.6.1 Procurement time

Preferably, after the allocation of all (non-renal) organs, a final time for the procurement should be agreed upon, taking into account the following

- donor family needs
- donor hospital needs
- travel time and availability of procurement teams.
- travel time
- Other logistical issues, like weather conditions both at the donor hospital and recipient center side

This time frame should be realistic and all parties involved must aim at strictly adhering to this time frame. Any reason to postpone this plan should be justified immediately.

If necessary, the transplant coordinator at the procurement center (host transplant coordinator) should contact the nearby (civil or military) airport to arrange for the landing and additional departure of the airplane(s) transporting the procurement team(s). In addition, transport from the airport to the donor hospital should be arranged according to the agreements made by the host and visiting transplant coordinator.

To ensure an optimal logistic plan the host transplant coordinator should be informed about the following details:

- expected time of arrival
- airport of arrival
- flight number
- size of the procurement team
- a contact number of the procurement team

Both size and the number of the procurement teams should be limited.

Upon arrival the following details should be made available to the procurement teams, especially to the procurement surgeon in the operation room at the time of procurement:

- Patient's identification

- Provide the complete and most recent donor information
- ABO-blood group confirmation form
- Death certification
- Consent for donation
- Assessment of risk factors and the general suitability of the donor

For thoracic teams the chest X-Ray and ECG should be reviewed.

9.2.6.2 *Procurement*

If there are unexpected findings during the surgical examination of the donor, the host transplant coordinator should provide the procurement teams as well as the Eurotransplant office with all the possible facilities to achieve a diagnosis (e.g. a liver biopsy before the start of organ cooling in case of hepatic steatosis). The final (pathology) findings should be sent to the Eurotransplant office as well as to the recipient center(s).

The procurement teams are responsible for the correct procurement of the organ(s), as well as the collection of cross-match material and other relevant samples.

The host transplant coordinator must take care that all organs procured by the local team are properly packed.

For more information please refer to the procurement guidelines 9.4.

9.2.6.3 *Donor follow up at procurement center*

The procuring surgeons are responsible for filling out the anatomy details and other findings noticed during the operation. This information is noted in the organ report(s). It is up to the host transplant coordinator to verify the completeness of these documents.

After the procurement has been completed, the host coordinator should file the donor information form and provide the anatomic data electronically or in exceptional cases send a copy of the donor organ reports to the Eurotransplant office as soon as possible.

9.2.6.3.1 *Right to choose a kidney*

Directly after receiving the anatomy, Eurotransplant contacts the transplant center that has the right to choose the kidney they prefer (left or right).

The right to choose which kidney the transplant center will receive, is done according to the following order:

1. Kidney in combination with another organ following the sequence under section 9.2.5
2. AM patient via the AM match
3. Rank order on the kidney match

9.2.6.4 *Packaging of organs that are forwarded to another transplantation center*

it is the responsibility of the local transplantation coordinator to organize who will check the packaging of an organ that is not transplanted in the local transplant center

(center where the organ is located) and forwarded to another transplantation center.,. This is done in mutual agreement with the local transplant center. Packing conditions of the organ are checked and corrected according to the guidelines. The following should be checked and corrected:

- Sufficient ice for the expected transport time to the next transplant center
- Sufficient cross match material and/or blood samples
- The completeness of the forms

9.2.7 Transport guidelines

9.2.7.1 *General*

In the transport guidelines you can find the general rules for transport within Eurotransplant.

9.2.7.2 *Quality of transport*

National or local authorities are responsible for the organ transport. In case the donor center / OPO cannot agree on the transport, the recipient center has the right to take over the responsibility of the transport.

9.2.7.3 *Transport of non-renal organs*

The host transplant coordinator or DSO are, in agreement with the transplant center, responsible for transport of deceased donor (non renal) organs and tissue typing material. Eurotransplant has no role in organizing the transportation of organs.

9.2.7.4 *Cross-border transportation*

Please be aware that proper identification is needed for all members of the procurement team in case the team has to travel cross border.

This applies for travelling to all countries within Eurotransplant; not only for countries that are not (yet) an EU member. Proper identification is required because personal identification can be asked at all times by various types of officials that are legally required to check the identity of international passengers (e.g. pilot, customs, military, etc.). Incidents have occurred within Eurotransplant that resulted in transport delay of the procurement team. To prevent such incidents every person of the procurement team must be able to identify oneself with a valid identification document (e.g. passport, identification card).

9.2.7.4.1 Thoracic organs

In (almost) all cases the thoracic organs are procured by the center that accepted the organ(s). Arrangement of transport from and to the donor hospital is done by the thoracic procurement team and shall be communicated with the host transplant coordinator. The host transplant coordinator will help with the coordination of the local transport (e.g. from and to airport).

Separate transport for the thoracic procurement team after organ procurement is an essential precondition due to restrictions of cardiac/pulmonary ischemic time restrictions.

9.2.7.5 *Transport of renal organs*

The form of transport (e.g car, plane etc.) of renal organs depends on the distance between donor and transplant center. Eurotransplant has a consultative role in finding a suitable flight for transport of renal organs.

The transport of renal organs to the airport of departure is organized by the host transplant coordinator. The transplant center is responsible for arranging the transport of the kidney from the airport of arrival.

9.2.7.5.1 Deviant national regulations

9.2.7.5.1.1 Germany and the Netherlands

Arrangement of transport from or to an airport in Germany (donor and/or transplant center is in Germany) is the responsibility of the DSO and not the responsibility of the donor or transplant center.

In the Netherlands, Nederlandse Transplantatie Stichting (NTS) is responsible for organ transport.

9.2.7.6 *Arrangement of transfers*

In case there is no direct flight possible, Eurotransplant will assist in arranging the transfer.

9.2.8 **Donor follow-up information from transplant center**

At the transplant center, the transplant surgeon is required to fill out the quality forms. These forms are used as feedback information for the donor center. The transplant surgeon can use these forms to give an evaluation on the quality of the organ (procurement) at the time of unpacking and, if executed, at implantation. Findings on anatomy, possible iatrogenic, transport of packaging related injuries, perfusion problems and initial organ function should be indicated.

In case of procurement or procedure related issues that threaten the suitability of an organ to be used for transplantation, the Eurotransplant Duty desk should be informed immediately.

Eurotransplant will then immediately discuss the problems with the physician in charge of the transplant center. He/she has to decide immediately whether or not the organ is still acceptable for the selected patient. If this is not the case, it has to be decided together with the transplant center and – depending on the individual situation and progress of the donation procedure – the donor center whether to continue the organ allocation as a recipient oriented extended allocation or a rescue allocation.

In all such cases, a copy of the organ quality form accompanied by a complaint letter has to be sent to the Eurotransplant Medical Staff and the OPO in charge of this procedure within one week. This letter will describe the cause of the possible/actual loss of the donor organ(s) for transplantation. These findings will be reported to the head of the involved transplant programs, the OPO and to the Medical Director of Eurotransplant. They will decide if further action is necessary and inform the Organ Procurement Committee if necessary.

If necessary, a letter of complaint should be sent to the visiting procurement team as well as to the Eurotransplant Department.

The host transplant coordinator can, at his discretion, send a letter to the donor hospital and the donor relatives informing them about the outcome of the procedure.

9.2.8.1 *Discarded Organs*

ET developed a Discarded Organ Application to register the discarded organs according to the rules of the policy as stated below.

Definition Discarded Organ

A discarded organ is an organ procured for transplantation, but no suitable recipient could be found or the organ is found not transplantable for any recipient.

Policy regarding discarding an organ (11)

1. If a procured organ cannot be transplanted for the selected recipient the center should contact ET immediately and only with approval of ET this organ can be discarded;
2. Discarding an organ shall only be permitted in one of the following ways:
 1. Leave the organ with the donor
 2. Use for donation of cells or tissues in case of consent
 3. Use for research after consent and confirmation of consent
 4. Send the organ for disposal
3. The following information regarding the discarded organ will be documented in the Discarded Organs Application *by the responsible person in a transplant center or organ procurement organization*:
 1. Reason for discarding the organ
 2. Name of person (in center / organ procurement organization) responsible for filling out the form
 3. Name and function of person deeming the organ as non-transplantable
 4. Address of the department or institute responsible for disposal of the organ
 5. Documentation of the discarded organ is the responsibility of the discarding transplant center / organ procurement organization and should be made available by the responsible parties as mentioned under C1-4, upon request.

9.2.8.2 *Potential risk factors(12)*

1. It is the responsibility of the procurement and the transplant centers to report all known transmittable diseases immediately report to Eurotransplant (e.g. infection, malignancy etc.)
2. Eurotransplant must inform all involved recipient and donor parties (e.g. transplant centers, coordinators, tissue typing centers etc.) as soon as the information from the donor center is available.
3. In a later phase, Eurotransplant will inform the competent authorities about the events.

11) Recommendation P-OPC01.14. Accepted 07/05/14

12) Recommendation ROPC02.10. Accepted 22/09/10

9.2.8.3 Traceability

The competent authorities or other centers involved in donor procedure keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal.

When the donor procedure is completed, all (electronic) donor information is collected and stored within these centers. This is stored for a minimum of thirty years to ensure full traceability.

9.3 Donor management

Organ preservation starts with an adequate donor management.

Optimal donor management, based on the most recent scientific developments, should maintain and restore adequate perfusion and oxygenation of the organs and tissues to facilitate a successful organ preservation, recovery and transplantation.

9.3.1 General guidelines

Donor management should be the responsibility of the doctor in charge of the ICU and/or emergency room, unless otherwise stated in the protocol of the local donor hospital.

Donor management is also discussed in section 9.2.2.3.

9.4 Thoracic and abdominal organ procurement agreements

9.4.1 Introduction

The EU Directive 2010/45/EU, article 6 “Organ Procurement”, describes the basic principles for procurement that all European Union (EU) countries need to adhere to. The directive indicates that procurement guidelines are the responsibility of each EU country. This also applies for all ET Member States.

Therefore the ET manual no longer contains extensive information on all the technical aspects of procurement methods. In the reference section of this chapter a list of procurement guidelines is present that can be consulted.

Section 9.4 includes general agreements that have been made and addressed in the OPCC for all the member states.

Only the specific agreement regarding the allocation rules, which have consequences for the technical parts of procurement surgery, will be included.

9.4.2 Procurement team

The training and certification of procurement surgeons are the responsibility of the national competent authorities.

9.4.2.1 Thoracic

The Heart and Lung Transplantation Donor procurement team generally consists of:

- Cardiac and/or thoracic surgeon who is/are suitably trained and certified in performing cardiothoracic donor operations
- If possible a trainee donor surgeon
- Donor perfusionist / technician

9.4.2.2 *Abdominal*

- 1 procurement surgeon
- 1 assistant
- 1 procurement nurse or coordinator (for back table and flush procedures)

9.4.3 **Equipment**

9.4.3.1 *Thoracic*

The procurement teams should bring their own equipment to avoid extra cost for the donor hospital.

9.4.3.2 *Abdominal*

If indicated and as needed teams should bring their own equipment.

9.4.3.3 *Other equipment*

For each abdominal organ:

- 3 sterile bags
- 1 ice box
- 1 small box for a piece of spleen
- 1 tube for clotted blood (at least 4 ml)
- 1 tube for EDTA blood (at least 4 ml)
- 1 tube for heparin blood (at least 4 ml)
- For tissue typing: 1 tube for EDTA blood (10ml each)

9.4.3.4 *Equipment for tool-kit*

For each abdominal organ (for the kidney if requested) 1 small sterile box (3 bags, container) for “tool-kit” reconstruction vessels (veins and the arteries) is needed. For liver and pancreas the veins and arteries may be added to the organ bags.

9.4.3.5 *Perfusion fluids*

All perfusion fluids with a Conformité Européenne (CE) label are permitted in the Eurotransplant area. Centers are asked to report any new perfusion fluids to Eurotransplant to add them to our database.

9.4.4 **Transport surgical team**

Arrangement of transport from and to the donor hospital is at the discretion of the thoracic procurement team and shall be communicated with the donor transplant coordinator. The donor transplant coordinator will help with local transport (e.g. to and from airport).

Separate transport for the thoracic procurement team after organ procurement is a necessary precondition due to restrictions of cardiac/pulmonary ischemic tolerance restrictions.

9.4.5 Communication

9.4.5.1 *Arrival in the donor hospital*

It is essential to present your team and communicate with all people involved in the retrieval process. The emphasis is on collaboration within a the multidisciplinary team and professionalism must be maintained at all times.

The host transplant coordinator will be present throughout the whole retrieval process to ensure that:

- The family's wishes are honored
- The retrieval process runs smoothly
- The relevant donor charts and documents, including certificate of brain death, blood group, serological results and organ donation consent (in countries where required legally) are accurately filled out.

Upon arrival the following details should be made available to the procurement teams, especially the procurement surgeon, in the operation room at the time of procurement:

- Patient's identification, ET no.;
- ABO-blood group confirmation form;
- Death certification;
- Consent for donation;
- Assessment of risk factors with the general suitability of the donor;

For thoracic team the chest X-Ray and ECG should be reviewed.

9.4.5.2 *In the operating room*

In the operating room the surgeon should introduce him- or herself and their team. Furthermore the surgeon needs to communicate with the other procurement team(s) scrub nurses, anesthesiologist and transplant coordinators concerning which organs are to be removed and following points need to be agreed upon:

- Donor heparinization;
- Vessels cannulation;
- Where to cut vascular structures;
- Use of unusual medicines.

After inspection and before procurement of the thoracic organs, the procurement surgeon should contact the consultant cardiothoracic surgeon at the recipient transplant center and discuss the findings. A decision will be made regarding the suitability of the organs. Pertinent information should include the past medical history, pharmacology, haemodynamic data, macroscopic appearance and performance of the heart, pulmonary gas exchange, and bronchoscopic appearance of the lungs. This comprehensive review will be the basis for any decision regarding acceptance or denial of the organs.

The recipient transplant coordinator will be contacted to confirm time and the suitability of the organs. Necessary arrangements at the recipient hospital can made. At this time, the explanting surgeon should be able to advise an approximate time for cross clamp application and the time that the organs will be ready to leave the donor hospital.

9.4.5.3 *Leaving the donor hospital*

The heart and lungs are the organs that are the most susceptible to ischemic injury, therefore the heart and/or lung team can leave prior to the closure of the donor. The only exception is if only a procurement of thoracic organs is performed. The cardiac and/or thoracic surgeon should express final thanks to members of the donor hospital and the other procurement teams who will continue with the final stages of the donor procedures.

Before departure, the cardiac and/or thoracic surgeon should ensure that all necessary paper work is completed as required by the donor transplant coordinator and write a short concise note in the donor's medical notes.

As soon as possible after starting the return journey, the recipient transplant coordinator should be informed of the estimated time of arrival at recipient hospital.

9.4.5.4 *Cross-match material*

The host transplant coordinator should take care of shipment of tissue typing and cross match material to the affiliated tissue typing laboratory. This is for the purpose of kidney transplantation or for other organ transplantation, and if indicated for other organs.

9.4.5.5 *Uniform identification organ, spleen and blood samples*¹⁵

Identical identification items should be written **on** the transport box as well as on the bags and the blood samples **inside** the transport box.

The following identification items are mandatory⁽¹³⁾

1. ET donor number
2. Blood group
3. Registration date of the donor to Eurotransplant (dd/mm/yyyy hh:mm)

Form 1.9 Human_organ_for_transport is available via the member site and can be used for identification.

9.4.6 **Procurement Guidelines**

Guidelines on procurement are defined by the national competent authority.

Eurotransplant underlines the importance of a high quality of organ procurement. This includes minimizing the ischemic times and optimal treatment of required vessels and other structures.

9.4.7 **Inspection**

9.4.7.1 *General*

Recommendation performing pathology research in case of tumor:¹

13) P-17001OPC17: Labeling of Cross Match Material

¹ Recommendation ROPC03.08. May 18. 2009

In case a tumor is found, it is strongly recommended to perform a pathology research to have a clear diagnosis on this tumor.

9.4.7.2 Abdominal organ inspection

Inspect all abdominal organs for:

- Tumor (malignancy)
- Infection
- Injury

9.4.7.2.1 Liver inspection

Examine the liver parenchyma for:

- Quality (steatosis, fibrosis, cirrhosis, edema)
- Injury (tear, haematoma)
- Tumor (benign, malignant)
- Infection (cholecystitis, cholangitis)

Examine liver arterial blood supply:

- Inspection of the Hepato-gastric and Hepato-duodenal ligament

9.4.7.2.2 Pancreas inspection

Surgical routes during pancreas inspection are going through the:

1. Hepatogastric ligament (can also be left intact)
2. Gastrocolic ligament
3. Detaching greater omentum from the transverse colon
4. Kocher maneuver (only head)

Remember: during pancreas inspection use the “no touch technique”.

Look for: interlobular edema, tumor, fibrosis, injury, hematoma and infection.

9.4.7.2.3 Kidney inspection

The procuring surgeon has the responsibility to perform a thorough inspection of the kidneys by removing all the perirenal adipose tissue. **See Figure 1.**

Examine the kidney for: anatomy, state of perfusion, tumor, injury and infection.

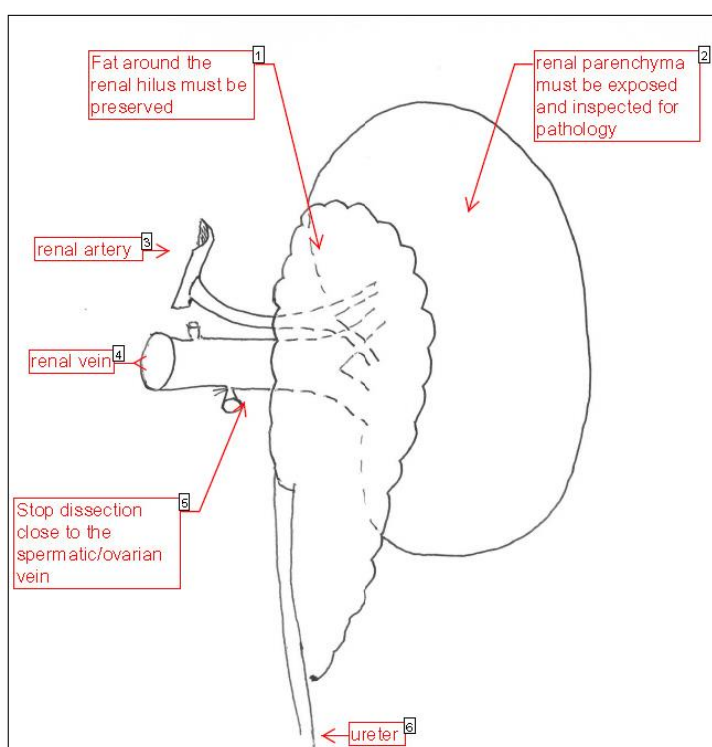


Figure 1: Inspection of the kidney and instructions for removing perirenal adipose tissue.

9.4.7.3 Cross-match material

After the organ retrieval, all organs are to be put into an ice filled transport box with a piece of spleen (or good quality lymph nodes* if no spleen is available) and blood specimen. The spleen and lymph nodes are to be put into tubes containing saline or Ringer's lactate solution which tubes are to be put into a labeled small box.

*para-aortic, small bowel or mesentery located

Another piece of spleen is used for tissue typing and cross matching. This piece of spleen is stored in the same way as described above.

Blood samples (clotted and EDTA), lymph nodes and/or spleen for each abdominal organ should be properly and identically identified.

9.4.7.4 standard vessels in the toolkit(14)

In order to prevent problems at the time of procurement the following agreements have been made between all relevant parties regarding the liver, intestine and pancreas procurement. The minimum of standard vessels needed for transplantation of the liver, intestine and pancreas need to be clarified.

The minimum of standard vessels in the toolkit in case of separate transplantation of liver, pancreas and intestine for transplantation should be:

- Intestine: iliac vessels (artery and vein) and bifurcation

14) P-LAC10.16: Intestine – minimum of standard vessels in the toolkit

- Pancreas: iliac vessels (artery and vein) and bifurcation
- Liver: common hepatic artery, celiac trunk
- Cannulation in the donor should be done at the level of the aorta

In case all three organs are going to be procured the liver center has to be informed about the limitation in the toolkit at time of acceptance.

9.4.8 Additional remarks

9.4.8.1 *Simultaneous intestine and pancreas procurement*

In the case of a simultaneous intestine and pancreas procurement, inferior pancreato-duodenal vessels have to be respected. Very early branching of the SMA (in rare cases) may be a contra-indication for simultaneous procurement and procurement of the intestine should be preferred. However, when complex anatomical situations present, en-bloc procurement with subsequent back table separation should be performed. The latter procedure shortens the donor procedure, however, prolongs cold ischemia time.

Procurement of the intestine is most often performed by the transplanting center and by experienced procurement surgeons.

1. Kocher maneuver
2. Cattell-Braasch maneuver
3. Exposure of abdominal aorta and ICV up to the SMA
4. Broad mobilization of the ligament of Treitz and distal duodenum
5. Transect the inferior mesenteric vein
6. Encircle the SMA
7. Encircle the aorta and ICV distally; ligation of IMA
8. Divide the gastrocolic omentum
9. Mobilize the left colon
10. Dissect the complete colon and expose the colic vessels
11. Complete colectomy after transection with GIA terminal ileum
12. Medial visceral rotation and mobilize the pancreatic tail / spleen
13. Division of highest jejunal arcades close to jejunal wall
14. Transect the proximal jejunum with GIA
15. Anterior exposure of superior mesenteric vessels by transverse dissection of the mesenteric root distal to the level of the middle celiac vessels
16. Transect the post pyloric duodenum with GIA
17. Ligate the left gastric artery, division of short gastric vessels to the spleen

Warning: Antegrade decompression of the intestine as proposed by some centers is discouraged due to mechanical stress

Please note: *If the pancreas is required for anatomical reasons in light of a multivisceral transplantation or modified multivisceral transplantation a request with justification for an ACO status should be filed (17)*

Please note: *In case at procurement of both intestine and pancreas proper procurement of both organs is not possible, the intestine graft has priority. In such cases a report is sent to ELIAC and to EPAC by the procuring surgeon.*

9.4.8.2 *Packaging*

All organs, as well as a tool kit, have to be packed separately in an ice filled transport box according to the following Eurotransplant regulations or to the national protocol.

9.4.8.3 *Reports on the procurement*

As organ procurement is an acknowledged surgical procedure, an operation report (for the donor center) as well as an organ report and organ quality form (for ET and recipient center), filled out and signed by the procurement surgeon in charge, is mandatory. His/her signature serves as the confirmation that the ET organ procurement rules are fulfilled.

A copy of the respective organ report, signed by the surgeon in charge, as well as an empty quality form per organ should be included in the transport box.

The host transplant coordinator is responsible for informing ET as soon as possible in case an organ is not procured. In case this rule is not followed it will be interpreted as a violation.

It is considered normal procedure to procure (a part of) the spleen for cross-matching in the recipient center. This should always be the case for kidney transplantation and might be relevant for other organs.

9.4.8.3.1 Documents

The shipping and medical documents should be placed in separate areas of the transport box: the shipping documents on the outside and the medical documents preferably inside the transport box (e.g. the area for XM material in the cover of the transport box).

9.4.8.3.2 Abdominal organs

Each organ is stored in three separate bags:

- The first bag is filled with 4°C preservation solution;
- The first bag is put into the second bag (or a wax impregnated fiber container) which is filled with cooled saline or Ringer's lactate solution;
- The second bag is put into the third bag. It is recommended to keep the third bag dry.

All bags are de-aired and well tied. The organ is put into a transport box and well covered with non-sterile melting ice.

The abdominal team is supposed to collect, pack and clear all equipment in such a way that any residues of the donor operation are efficiently cleared.

In case only a thoracic procurement takes place, the thoracic team is responsible for the closing the donor.

17) R-LAC07.16: Intestine – ACO status request including pancreas for anatomical reasons

18) PLAC08.16 Intestine and pancreas procurement.

9.4.8.3.3 Machine Perfusion

Machine perfusion can provide an alternative way to preserve organs from donor to recipient. The donating and transplanting center should discuss this matter.

9.5 Serious Adverse Events & Serious Adverse Reactions

As of Spring 2014, the EU Directive 2012/25 specifies the need for an information transfer system collecting Serious Adverse Events and Serious Adverse Reactions (SAE / R) in the European Union Member states with a link to tissues and cells.

9.5.1 Definitions EU Directive 2012/25

Serious Adverse Event:

A serious adverse event (SAE) is defined as any undesired and *unexpected* occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity.

Serious Adverse Reaction:

A serious adverse reaction (SAR) is defined as an *unintended* response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalization or morbidity.

9.5.2 Role Eurotransplant

In order to facilitate the ET member states to implement the requirements, ET has introduced a procedure for the SAE/R.

Upon notifying a SAE/R to ET - by phone or document - (please check the EU Directive for definitions) the allocation duty officer will ask you to complete a form and submit it to ET. Both forms for SAE/R can be found on the ET member site:

https://members.eurotransplant.org/cms/index.php?page=library_forms_gen

The procedure for SAE/R is as follows:

- ET sends a SAE/SAR form to the reporting organization
- ET collects all necessary information to enter in an Access database and to prepare an initial report
- ET drafts an initial report and send it to the National Competent Authority (NCA)
- NCA is responsible for making a final report.
 - Transplant centers with recipients that accepted and transplanted an organ from a donor with a SAE will be informed by a letter.

On the member site a the contact list for all EU member states is available.

9.5.3 Standardized reporting of Micro-organisms (MO)

Within Eurotransplant, variability exists in the reporting of infections or presence of micro-organisms (MO) in Broncho-Alveolar Lavage and transport fluids. Some of

these MOs require specialized multi-drug treatment and can severely influence outcomes regarding transplantation. A list of MOs has been constructed to provide guidance for the reporting of SAE/Rs. Thus, by differentiating the SAE/R from AE/R, both the over- and underreporting of SAE/Rs will be resolved.

To be reported as SAE/SAR:

Multi-resistant germs and fungi, e.g.

- MRSA
- VRE
- 3- and 4-MRGN
- Pseudomonas aeruginosa.
- Candida albicans and other Candida species., Aspergillus etc.

In-depth analysis for these MOs for the DSO is available from:

<https://www.dso.de/organspende/fachinformationen/sae-sar-meldung#dropdown-statistiken-berichte>.

9.6 Forms

All forms can be found and downloaded from the section 'Forms' of the member site at www.Eurotransplant.org.