

Chapter 7

ET Pancreas Allocation System (EPAS)

Change record

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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 transplant candidates 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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7.1.1.1.1.1 EPAS – Listing

7.1.2 Listing criteria

A diabetic patient can be listed on the ET pancreas active waiting list if the β -cell antibody screening (IA-2-, ICA- and/or GAD) is positive or has been positive in the past.

In case of a negative β -cell antibody screening, a stimulation test has to be performed. Listing on the active waiting list is allowed if the C-peptide value is ≤ 0.5 ng/ml without an increase of $>20\%$ after stimulation.

If a patient does not fulfill one of the above criteria but is still regarded having insulin-dependent diabetes by the treating physician, then a special request for listing on the active waiting list should be sent to ET together with the clinical history and data of the patient. The request will be evaluated by members of the ET Pancreas Advisory Committee (EPAC). Listing of such a patient on the active waiting list can be performed upon approval by the EPAC.

7.1.3 Required type of Transplant

Transplant candidates can be listed either for Vascularized Pancreas Transplantation or Islet Transplantation. Islet Transplantation is only performed in designated centers

7.1.4 Urgency codes

Urgency codes are used to classify patients on the waiting list and to prioritize the patients in the match and allocation procedure. Urgency codes reflect transplantability and medical urgency.

Urgency codes on the waiting list for a pancreas transplant

| Urgency code | | Transplantability | Medical urgency |
|--------------|--|-------------------|------------------------|
| ACO | Approved Combined Organ (mandatory exchange) | yes | multi-organ transplant |
| SU | Special Urgency | yes | urgent |
| T | Transplantable | yes | elective |
| NT | Not Transplantable | no | no |

7.1.4.1 Approved Combined Organ (ACO)

Patients in need of a multi-organ pancreas transplant (except pancreas + kidney) can request an ACO status.

A remote center cannot assign an ACO status in ENIS.

7.1.4.1.1 ACO audit

An ACO audit can only be initiated when the transplant candidate is on the active waiting list for all organs concerned (except for pancreas: Not transplantable due to too high C-peptide). The corresponding ACO forms (see [Eurotransplant ACO Forms](#)) must be completed on all items, with a complete and appropriate documentation and justification in English, and are then sent to: The request is then sent to one member of the EPAC and, depending on the other organ(s), one member of (an) organ-specific advisory committee(s) (liver, intestine [ELIAC], thoracic [EThAC]). Both members must be from outside the requesting center and will be given 24 hours to reach their decision. In a tie situation, a third member will decide on the approval or denial of the ACO request. All ACO requests requiring a pancreas will be audited by a member of the EPAC. Approved ACO requests will be allocated according the leading organ (See Chapter 3 Allocation general §3.2.3).

7.1.4.2 Special Urgency (SU)

7.1.4.2.1 Vascularized Pancreas Special Urgency (SU) status

Any Eurotransplant pancreas transplant center can request the Vascularized Pancreas Special Urgency (SU) status for a transplant candidate on the active waiting list (i.e. SU requests will not be taken into account for transplant candidates still in urgency NT).

- The Vascularized Pancreas Special Urgency (SU) status is an international status and is valid for three months or until the transplant candidate receives a status other than active within that time period.
- Transplant candidates with a Vascularized Pancreas Special Urgency (SU) status will be allocated prior to the transplant candidates with an elective status.

Inclusion criteria:

- Vascularized pancreas graft failure within two weeks after (combined) vascularized pancreas transplantation, with re-registration and SU requested within two weeks after transplantation.
- A defective glycemic counter regulation confirmed by a hypoglycemic clamp test
- Suffering from hypoglycemia unawareness at least twice in one year, requiring medical assistance and hospitalization;

7.1.4.2.1.1 Deviant national Regulations: Germany

- Either experiencing two or more hypoglycemic episodes in one year requiring medical assistance or one confirmed episode of hypoglycemic unawareness.

7.1.4.2.2 Islets Special Urgency (SU) status

A SU status can be requested for islet transplantation in non-German countries.

The SU islet status is a national status and valid until the transplant candidate receives a status other than active within that time period.

The national SU status is granted according to the national criteria described for each member country in 7.8.1 National SU islet criteria.

7.1.4.3 SU audit

The corresponding SU form (see [Eurotransplant SU Pancreas Forms](#)) must be completed on all items and sent to: urgency@eurotransplant.org. All requests are evaluated by members of the Eurotransplant Pancreas Advisory Committee.

For Vascularized Pancreas SU status two members of the EPAC, from outside the requesting center, are contacted to evaluate the SU request according to the above mentioned criteria, and only after its approval will urgency SU be granted and will the urgency be changed in ENIS by the ET Medical Administration. In a tie situation, a third EPAC member will decide on the approval or denial of the SU request.

In case of doubt in a combined vascularized pancreas-kidney SU request concerning the indication for the kidney transplant, an ETKAC member can be asked for advice¹.
Islet Special Urgency (SU) status can be audited by the Eurotransplant medical staff. In case a request for does not fulfill the national criteria, the request is sent to the national Auditor.
A transplant center cannot assign urgency SU in ENIS.

7.1.4.4 SU status re-evaluation

The time limit for the vascularized pancreas SU status is set to three months. If a patient has not been transplanted within this time frame and the transplant center involved wants to prolong the SU status, the center will have to submit a renewed request accompanied by a comprehensive letter in English language. The request will be audited by the pancreas audit committee².

A renewed request should preferably be submitted 3 days before the end of the SU period. If the renewed request has not been sent in by the end of the SU period, the patient will be downgraded to the T status the next day.

Patients in SU status who become (temporarily) not transplantable have to be reported as NT to Eurotransplant and will at that moment lose the SU status and the SU days accumulated so far. If these transplant candidates become transplantable again, a new SU request has to be sent to Eurotransplant.

7.1.5 Transplantable (T), elective patients

Urgency T is used for elective patients awaiting a vascularized pancreas or islet transplant and who are transplantable.

7.1.6 Not Transplantable (NT)

Urgency NT is used for patients who are temporarily not transplantable. All previously accumulated waiting time in an active status (T or SU) is retained during the NT status.

During one single waiting list period, patients can accumulate waiting time points up to 30 days in the NT status. These waiting time points will only be used in urgency T. Following these 30 NT days, no further waiting time points in the NT status are added to the total waiting time period.

Patients with urgency NT are not selected in matching procedures.

7.2 EPAS - general

7.2.1 Donor criteria

Donors with age ≥ 5 and ≤ 50 years and with BMI < 30 Kg/m² are selected for vascularized pancreas transplantation. Donors with age < 5 or > 50 years or with a BMI ≥ 30 Kg/m² are considered extended criteria donors and selected for islet transplantation. For deviant national regulations see 7.2.2.5 Deviant national regulations

7.2.2 EPAS – Allocation Algorithm

This section describes the allocation of a donor pancreas to those transplant candidates awaiting either a pancreas-only (vascularized or islet) transplantation, or a simultaneous vascularized pancreas kidney or islet kidney transplantation.

¹ Board recommendation RPAC01.11; EPAC meeting October 2011

² Board recommendation RPAC02.08 : EPAC meeting October 2008

Transplant candidates awaiting transplantation in combination with either thoracic organs or the liver are considered in this other organ allocation algorithm. Please refer to the respective organ specific chapter at [Eurotransplant Manual](#).

Pancreas-kidney transplant candidates will not be favored over pancreas-only transplant candidates in the allocation.

The EPAS Allocation algorithm consists of:

- Transplant candidate selection (see 7.2.2.1)
- Transplant candidate ranking (see 7.2.2.2)
- Filtering on donor profile (see 7.2.2.4)

7.2.2.1 Transplant candidate selection

The selection of potential transplant candidates is based on Required type of Transplant, donor age, donor body mass index (BMI=weight [in kilograms] / (height [in meters])²), and ABO blood group rules.

Pancreas of donors aged ≥ 5 and ≤ 50 years with a BMI of $< 30\text{Kg/m}^2$ are primarily offered to transplant candidates awaiting a vascularized pancreas transplantation and thereafter to transplant candidates awaiting an islet transplantation.

Pancreas of donors age either < 5 years or > 50 years or with a BMI $\geq 30\text{Kg/m}^2$ are offered to transplant candidates awaiting an islet transplantation only.

If HLA is known, highly immunized (PRA $> 85\%$) pancreas + kidney transplant candidates accepted within the AM kidney program will receive an organ offer via the AM program (see [ETRL Website](#)). These pancreas-kidney-transplant candidates are prioritized over other transplant candidates within the same urgency tier (SU, T)

7.2.2.1.1 ABO blood group rules

In all countries the allocation is blood group identical before compatible and national before international³.

ABO-incompatible pancreas transplants are not allowed.

7.2.2.1.1.1 ABO identical

| Donor blood group | Eligible transplant candidates |
|-------------------|--------------------------------|
| A | A |
| B | B |
| AB | AB |
| O | O |

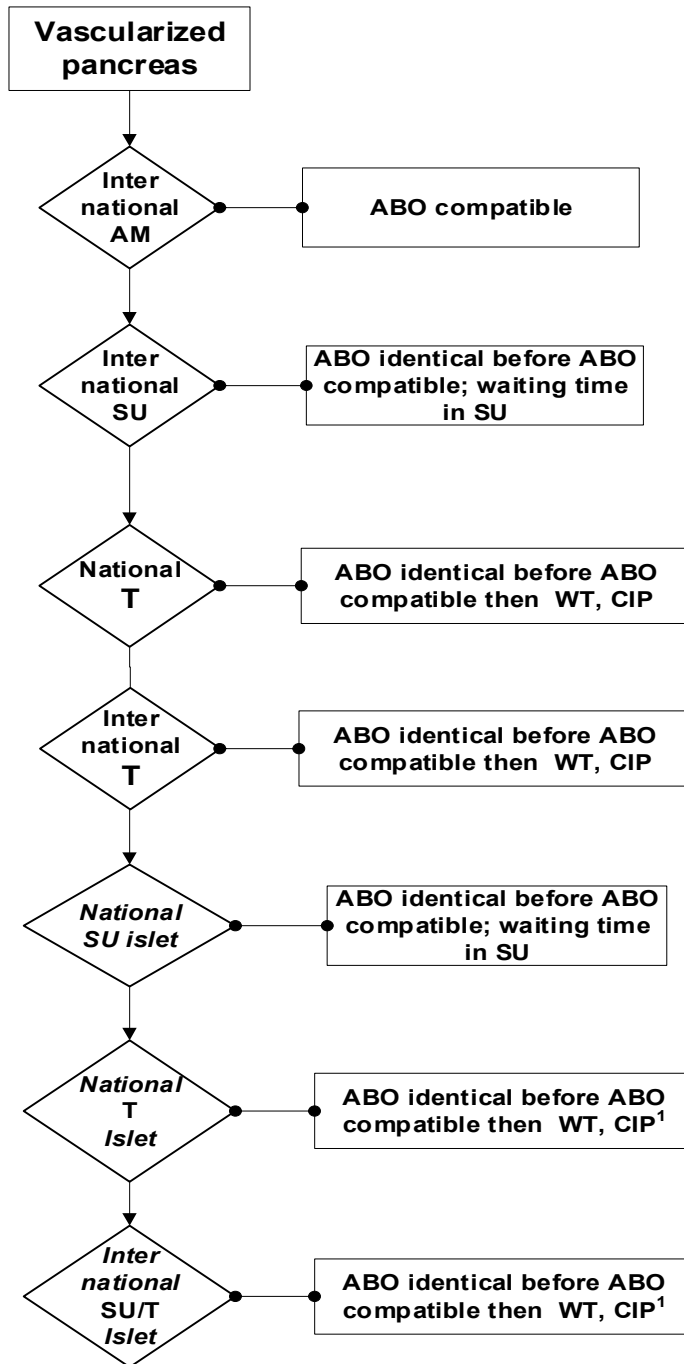
³ As per 9 December 2013 all countries follow the same blood group rules (RPAC02.11)

7.2.2.1.1.2 ABO compatible

| Donor blood group | Eligible transplant candidates |
|-------------------|--------------------------------|
| A | A and AB |
| B | B and AB |
| AB | AB |
| O | O, A, B, AB |

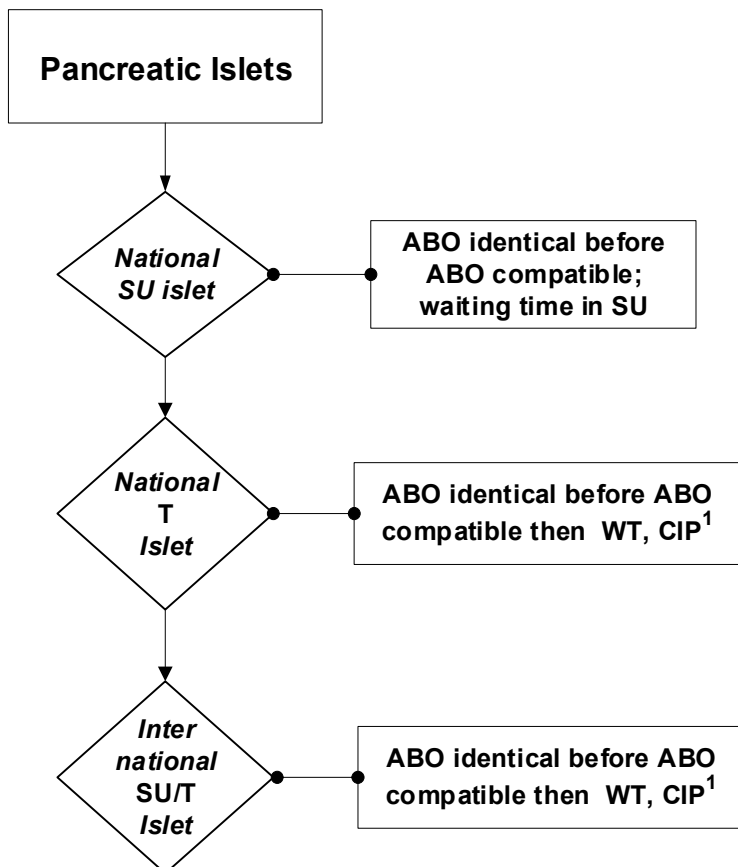
7.2.2.2 Transplant candidate Ranking

7.2.2.2.1 Flowchart 1 - Vascularized pancreas allocation.



1 Center offer according to the highest ranked recipient

7.2.2.2.2 Flowchart 2 – Pancreatic islet allocation



2 Center offer according to the highest ranked recipient

7.2.2.2.3 Point score system

Elective (T) transplant candidates are ranked, within the ABO blood group rules with the help of a point score system. In order to keep the cold ischemia as short as possible, points are added to the waiting time when the donor and the transplant candidate share a region (See 7.2.2.2.3.2):. The transplant candidate with the highest point score is ranked on top of the tier concerned. All offers, primary or back-up, are made in descending order. Points are assigned as follows:

- Waiting time (see 7.2.2.2.3.1):
 - 1 point/day
- Distance:
 - Same Region
 - 0.67 x Waiting time points
 - Other Region:
 - 0 points
- Pancreas exchange balance

In case a pancreas cannot be allocated nationally, it will be offered to the other ET member states. In this case in addition to the waiting time points pancreas exchange balance points will be considered for the ranking:

7.2.2.2.3.1 Waiting time

For every day on the waiting list, the transplant candidate is given one point. Waiting time starts with the first day that the transplant candidate had an active urgency. While in urgency NT transplant candidates can accumulate waiting time points for a maximum of up to 30 days during their total waiting time period (see 7.1.6)

7.2.2.2.3.2 ET countries/regions

The Eurotransplant region is divided into 6 countries for pancreas procurement. In addition, Germany further is divided into 7 procurement subregions.

To minimize the CIP, national transplant candidates are prioritized over international transplant candidates.

Pancreas transplant candidates in the same German region as the donor achieve region calculated points in the match to reduce the cold ischemic period. See 7.2.1

7.2.2.2.3.2.1 Austria/Slovenia

Austria and Slovenia are considered one procurement region.

7.2.2.2.3.2.2 Belgium/Luxemburg

Belgium and Luxemburg are considered one procurement region as Luxemburg has no pancreas transplantation program.

7.2.2.2.3.2.3 Germany

Germany consists of the following seven donor subregions:

| | |
|-------|---------------------|
| GBYOR | Bayern |
| GBWOR | Baden-Württemberg |
| GMIOR | Mitte |
| GOSOR | Ost |
| GNOOR | Nord-Ost |
| GNDOR | Nord |
| GNWOR | Nordrhein-Westfalen |

7.2.2.2.3.2.4 Other memberstates

All other member states (Croatia, Hungary and The Netherlands) are considered individual

procurement regions.

7.2.2.3 National Net Pancreas Exchange Balance

Once every day the national balance is calculated over a 365 days period prior to the respective day. Individually for each ET country⁴ a national balance is calculated.

The national balance is calculated as import minus export.

**Import* is defined as the number of pancreas transplanted within the country and procured outside the respective country

**Export* is defined as the number of pancreas transplanted outside the country and procured within the respective country

Formula:

National Balance Points = (highest current national balance of all pancreas transplanting countries – transplant candidate country balance) x 10

Example of the pancreas exchange balance on a certain day:

| | |
|----------------------|-----|
| - Austria+Slovenia | -4 |
| - Belgium+Luxembourg | -5 |
| - Netherlands | -2 |
| - Croatia | -1 |
| - Germany | +12 |
| - Hungary | 0 |

The balance points for transplant candidates in the countries of regions as mentioned:

| | |
|----------------------|-------------------------------|
| - Austria+Slovenia | $(12 - (-4)) \times 10 = 160$ |
| - Belgium+Luxembourg | $(12 - (-5)) \times 10 = 170$ |
| - Netherlands | $(12 - (-2)) \times 10 = 140$ |
| - Croatia | $(12 - (-1)) \times 10 = 130$ |
| - Germany | $(12 - 12) \times 10 = 0$ |
| - Hungary | $(12 - 0) \times 10 = 120$ |

Since all national transplant candidates are offered prior to the international allocation, the balance points only count after the national transplant candidates tier.

7.2.2.4 Filtering on donor profile

For the individual transplant candidate or the entire waiting list centers can enter donor specific requirements like Age, Virology, Other transmittable diseases etc. For further information see Chapter 3 Allocation. § 3.2.2I

7.2.2.5 Deviant national regulations

7.2.2.5.1 Austria

⁴ In the calculation of the National Net Pancreas Exchange Balance, Belgium & Luxemburg resp. Austria & Slovenia are considered as one country.

Organ offers from Austrian donors are center offers for the donor center or the assigned center. If a pancreas can't be allocated in the donor center, ET shall offer the pancreas patient-oriented according to the match list

7.2.2.5.2 Belgium

The HLA-typing is mandatory for the pancreas allocation.

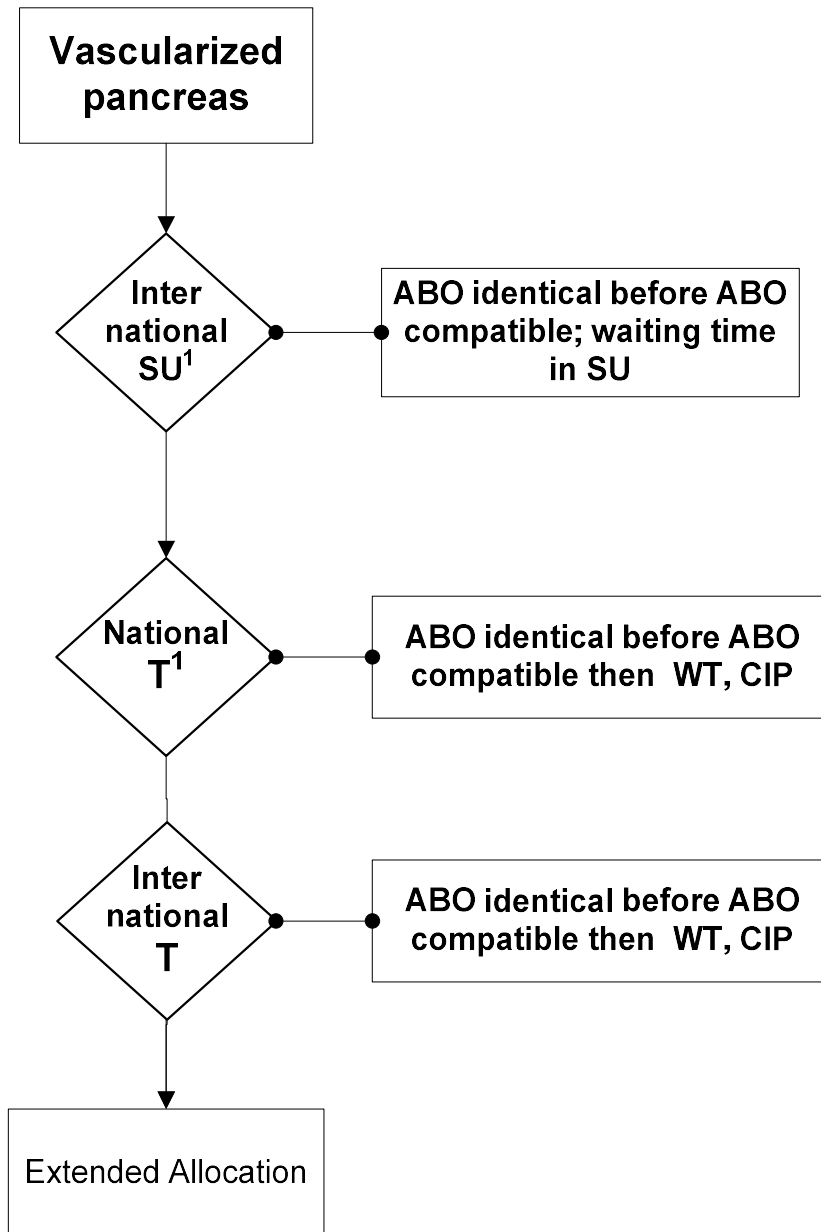
In case of a Belgian donor the allocation starts as soon as HLA is known. In case of a non-Belgian donor without HLA-typing at the time of offering, only the Belgian ACO and SU transplant candidates will receive an offer. Belgian transplant candidates in urgency T will be excluded from the allocation in case of a non-Belgian donor without HLA-typing at the time of offering.

7.2.2.5.3 Germany

Islets are considered in Germany as tissue, therefore the German pancreas donors with age < 5 or age > 50 years or BMI ≥ 30 are not offered for islet transplantation. They will be allocated (after offering to ACO or SU transplant candidates) as extended criteria donors according to the vascularized pancreas extended allocation (see 7.2.2.5.3.2). If an Extended Allocation was not successful, a center-oriented rescue allocation will be started.

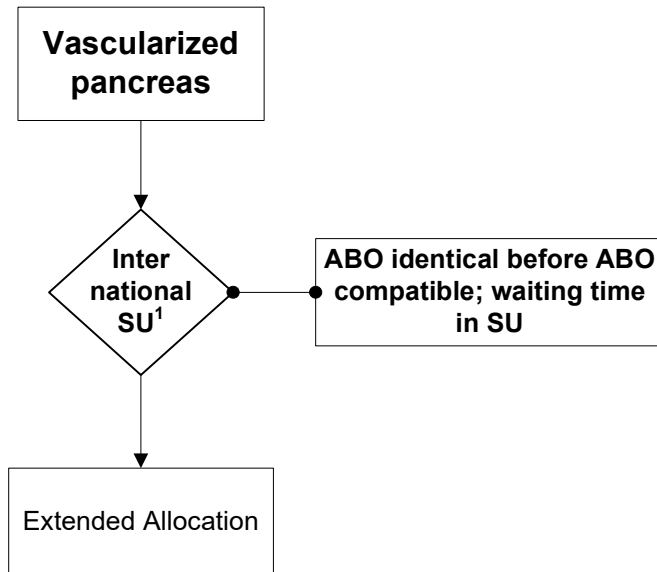
Non-German islet-donors will not be offered to German transplant candidates.

7.2.2.5.3.1 Flowchart 3 - Vascularized pancreas allocation German donor ≥ 5 and ≤ 50 years and BMI < 30



¹ if HLA known at time of match then internationall ,ABO compatible (SU/T) vascularized pancreas transplant candidates selected by the AM match with positive advice first

7.2.2.5.3.2 Flowchart 4 - Vascularized pancreas allocation German donor ≥ 5 and ≤ 50 and BMI ≥ 30 ; or > 50 years



¹ if HLA known at time of match then international, ABO compatible (SU/T) vascularized pancreas transplant candidates selected by the AM match with positive advice first

7.2.2.6 The Netherlands

The maximum age limit of a Dutch DBD vascularized pancreas donor is 60 years, therefore all Dutch DBD donors ≤ 60 years are allocated as vascularized pancreas donors.

7.3 P-PASS

The P-PASS (Preprocurement Pancreas Allocation Suitability Score) has been implemented in 2009 in order to facilitate recognition of a suitable pancreas donor. A combination of 9 clinical parameters available at time of donor reporting, including age, BMI, ICU stay, cardiac arrest, sodium, amylase, lipase, (nor)adrenaline and dobutamine/dopamine are calculated, providing a P-PASS score between 9 and 27 for each donor. Study⁵ showed pancreas donor acceptance with P-PASS < 17 three times higher than pancreas donors with P-PASS equal or above 17.

In Eurotransplant at least all donors with a P-PASS < 17 pancreas should be considered for donation and transplantation.

⁵ How to recognize a suitable pancreas donor: a Eurotransplant study of preprocurement factors, Vinkers MT, Rahmel AO, *Transplantation Proceedings*, 40, 1275-1278 (2008)

7.3.1 P-Pass factors

| Item | 1 point | 2 points | 3 points |
|--|--------------|--------------------|----------------|
| Age (years) (x2) | <30 | 30-40 | ≥ 40 |
| BMI (kg/m ²) (x2) | <20 | 20-25 | ≥ 25 |
| ICU-stay (days) | <3 | 3-7 | ≥ 7 |
| Cardiac arrest (min) | No | Yes, < 5 | Yes, ≥ 5 |
| Sodium (mmol/L) | <155 | 155-160 | ≥ 160 |
| Amylase (U/l) or Lipase (U/l) | <130 <160 | 130-390 160-480 | ≥ 390 ≥ 480 |
| (Nor)adrenaline (γ) or Dobuta-/Dopamine (γ) | No No | < 0.05 < 10 | ≥ 0.05 ≥ 10 |

7.4 Combined Pancreas intestine procurement

If from one donor both pancreas and intestine are reported to ET, the intestine will always be allocated first. In case of an adult donor intestine and pancreas should always be offered both (if both organs were reported to ET). Every effort should be made to prevent loss of the pancreas for anatomical/surgical and/or logistical reasons⁶.

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 surgeon⁷.

7.5 Allocation of vessels in the toolkit

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
- 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 acceptance⁸.

7.6 Allocation of the Donation after Cardiocirculatory Death (DCD) donor

The Netherlands have a Donation after Cardiocirculatory Death (DCD) pancreas transplantation program, including vascularized pancreas (donor age ≤ 50 years and BMI < 30 Kg/m²) and pancreatic islets transplantation.

Belgium has a DCD pancreatic islets transplantation program. The other Eurotransplant countries do not perform DCD vascularized pancreas or islets transplantation.

⁶ Recommendation R-LAC02.09

⁷ Policy P-LAC08.16, result of the intestine allocation consensus meeting June 22, 2016

⁸ Policy P-LAC10.16, result of the intestine allocation consensus meeting June 22, 2016

7.7 Forms

All forms can be found and downloaded from the section Forms of the Library of the member site at [Eurotransplant Pancreas Forms](#).

7.8 Appendix

7.8.1 National SU islet criteria

7.8.1.1 Belgium

SU status for islets should be granted to type 1 diabetic patients who:

- Need re-transplantation within a shortest time possible because of an insufficient primary graft yield and
- Participate in a clinical islet transplant study aiming at efficacy as primary endpoint. The protocol of the study must be submitted to an institutional review board and ethical committee.

The letter of SU should explain the need for re-transplantation and includes the name of the study, an official registration number (EutraCT or other) and the approval by a review board and ethical committee.

7.8.1.2 Other countries

No national SU islet criteria are indicated by the Netherlands or Austria

7.8.2 Pending recommendations

| Number | Description | Date approval board | Status |
|------------|---|---------------------|--|
| R-PAC01.14 | Adaptation of pancreas listing criteria | January 2015 | Pending authorization Germany |
| R-PAC01.15 | Plasmapheresis immunized program | January 2016 | Pending authorization in more than 1 country |
| R-PAC01.16 | SU status and return of waiting time after early failed pancreas transplant | May 2016 | Pending authorization in more than 1 country Adaptation requested by German NCA |
| R-PAC02.16 | Categories of pancreas donors | January 2017 | Pending authorization in more than 1 country |
| R-PAC01.17 | list registration and calculation of waiting time | May 2017 | Pending authorization in more than 1 country |
| R-PAC01.18 | Immunized program for pancreas recipients | May 2018 | Pending authorization in more than 1 country |
| R-PAC02.19 | Revision of SU inclusion criteria | May 2019 | Pending authorization in more than 1 country |