

Chapter 7

ET Pancreas Allocation System (EPAS)

Change record

Date	Author	Version	Change reference
Dec 2011	MD van Rosmalen	1.1	7.1.2.1.1 Adaptation ACO-audit; all pancreata need to be audited, even pancreata with positive antibodies or impaired hypoglycemia according to decision EPAC 13-10-11
Aug 2012	MD van Rosmalen A Verweij	2.0	Total revision

Chapter 7 – EPAS

Table of contents

7.1	EPAS – URGENCY CODES	4
7.1.1	Listing criteria	4
7.1.2	Urgency codes	4
7.1.2.1	Approved Combined Organ (ACO)	4
7.1.2.2	Special Urgency (SU)	5
7.1.2.3	SU audit	6
7.1.2.4	SU status re-evaluation	6
7.1.3	Transplantable (T), elective patients	7
7.1.4	Not Transplantable (NT)	7
7.2	EPAS - GENERAL	8
7.2.1	Point score system	8
7.2.2	National Net Pancreas Exchange Balance	9
7.2.3	Waiting time	10
7.2.4	ET countries with regions	10
7.2.4.1	Austria/Slovenia	10
7.2.4.2	Belgium/Luxemburg	10
7.2.4.3	Germany	10
7.2.4.4	The Netherlands	10
7.2.4.5	Croatia	10
7.2.5	P-PASS	11
7.2.5.1	P-Pass factors	11
7.2.6	ABO blood group rules	12
7.2.6.1	ACO-recipients (international)	12
7.2.6.2	SU-recipients (non-German donors)	12
7.2.6.3	Elective recipients (non-German donors)	12
7.2.6.4	SU recipients (German donors)	12
7.2.6.5	Elective recipients (German donors)	13
7.2.7	Deviant national regulations	14
7.2.7.1	Belgium	14
7.2.7.2	Germany	14
7.2.7.3	The Netherlands	14
7.3	EPAS – ALLOCATION ALGORITHMS	15
7.3.1	Vascularized pancreas allocation	16
7.3.1.1	Vascularized pancreas allocation non-German countries	16
7.3.1.2	Vascularized pancreas allocation Germany	18
7.3.2	Pancreas islet allocation	20
7.3.3	Non heart beating donor allocation	21
7.4	FORMS	22
7.5	APPENDIX 1	23
7.5.1	National SU islet criteria	23
7.5.1.1	Belgium	23
7.5.1.2	Other countries	23

7.1 EPAS – urgency codes

7.1.1 Listing criteria

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

In case of a negative islet antibody screening, a glucagon stimulation test has to be performed. Listing is allowed if the c-peptide value is ≤ 0.5 ng/ml without an increase of $>20\%$ after glucagon 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 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 can be performed upon approval by the EPAC.

7.1.2 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

7.1.2.1 *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.

7.1.2.1.1 ACO audit

The corresponding ACO forms (see Forms at www.eurotransplant.org) must be completed on all items, with a complete and appropriate documentation and justification in English, and are then sent back to the ET duty desk. 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 country 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 to the leading organ.

7.1.2.2 *Special Urgency (SU)*

7.1.2.2.1 SU Vascularized pancreas transplantation

A SU status can be requested for vascularized pancreata in all ET countries. The SU vascularized pancreas status is an international status and is valid for three months. Recipients with an international SU vascularized pancreas status will be allocated prior to the recipients 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 glycaemic counter regulation confirmed by a hypoglycaemic clamp test
- Patient suffering from hypoglycaemia unawareness at least twice in one year, requiring medical assistance and hospitalization;
 - In Germany: either suffering two or more hypoglycaemic episodes in one year requiring medical assistance or one confirmed episode of hypoglycaemic unawareness.

Exclusion criteria

Each of the following criteria represents a possible rationale for exclusion.

- Age < 18 years or > 65 years;
- Duration of Diabetes Mellitus <10 years;
- Creatinine Clearance <60 ml/min;
- Lack of supervision by a diabetologist;
- Lack of diabetes education, insufficient documentation of blood glucose values;
- Other general contraindications against organ transplantation.

7.1.2.2 SU Islets transplantation

A SU status can be requested for islet transplantation in non-German countries. The SU islet status is a national status and valid for an unlimited time until transplantation. Both can be requested for pancreas only and for pancreas-kidney combined. The national SU status is granted according to the national criteria. National inclusion criteria for each member country are described in Appendix 1. In case the request does not fulfill the national criteria, the request is sent to one national Auditor.

7.1.2.3 SU audit

The corresponding SU form (see Forms at www.eurotransplant.org) must be completed on all items and sent back to the ET duty desk. All requests are evaluated by members of the Eurotransplant Pancreas Advisory Committee. Two members of the EPAC, from outside the country of 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. 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 advice.¹

A remote center cannot assign urgency SU in ENIS.

7.1.2.4 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 committee.²

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 so far accumulated SU days. If these recipients become transplantable again, a new SU request has to be sent to Eurotransplant.

¹ Board recommendation RPAC 01.11 EPAC meeting October 2011

² Board recommendation RPAC02.08

7.1.3 Transplantable (T), elective patients

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

7.1.4 Not Transplantable (NT)

Urgency NT is used for patients who are temporarily not transplantable. All previously accumulated waiting time is retained in NT.

Patients can accumulate waiting time points for a maximum of up to 30 NT days during their total waiting time period on the waiting list.

Patients with urgency NT are not selected in matching procedures.

7.2 EPAS - general

7.2.1 Point score system

The selection of potential recipients is based on donor age, body mass index (BMI=weight [in kilograms] / (height [in meters])²), ABO blood group rules, medical urgency, waiting time and donor region.

Selected potential recipients are ranked with the help of a point score system. The patient with the highest point score is ranked on top and receives the first offer. All following offers, firm or back-up, are made in descending order. Points are assigned as follows:

Factor	Remark	Weight in allocation
Waiting time (WT) (no maximum)	per active waiting day	1 point/day
Same region*	Cold Ischemia Period	WT points x 0.67

*Only applicable for the elective recipients.

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

Factor	Remark	Weight in allocation
National Net Pancreas Exchange Balance*	donor/patient in different countries	Formula see 7.2.2

Donors with age ≥ 5 and ≤ 50 and with BMI <30 are considered for vascularized pancreas transplantation. Donors with age > 50 or with a BMI ≥ 30 are considered extended criteria donors and eligible for islet transplantation. For deviant national regulations see 7.2.7

If HLA is known, highly immunized (PRA $> 85\%$) patients waiting will receive an organ offer via the kidney AM program. These pancreas-kidney-recipients have preference over other recipients within the same urgency tier (SU, T)

Regulations concerning the crossmatch and the Acceptable Mismatch program are described in Chapter 10 Histocompatibility Testing.

7.2.2 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 country (considering Austria and Slovenia respectively Belgium and Luxemburg for balances as one country)³ a national balance is calculated.

The national balance is calculated as import minus export.

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

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

Formula:

National Balance Points = (highest current national balance of all pancreas transplanting countries – recipient 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

The balance points for recipients 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	$12 - 12 \times 10 = 0$

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

³

In the calculation of the National Net Pancreas Exchange Balance, Belgium & Luxemburg, Austria & Slovenia are considered individual countries.

7.2.3 Waiting time

For every day on the waiting list, the patient is given one point. Waiting time starts with the first day that the patient had an active urgency.

7.2.4 ET countries with regions

The Eurotransplant region is divided into 5 countries for pancreas procurement with Germany further being divided into 7 regions. To minimize the CIP, national recipients are prioritized over international recipients. Pancreas recipients in the same region as the donor achieve region calculated points in the match to reduce the cold ischemic period. See 7.2.1

7.2.4.1 Austria/Slovenia

Austria and Slovenia are considered one procurement region.

7.2.4.2 Belgium/Luxemburg

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

7.2.4.3 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

7.2.4.4 The Netherlands

The Netherlands are considered one procurement region.

7.2.4.5 Croatia

Croatia is considered one procurement region.

7.2.5 P-PASS

The P-PASS (Preprocurement Pancreas Allocation Suitability Score) is implemented in 2009 in order to facilitate recognition of a suitable pancreas donor. A combination of nine clinical parameters available at time of donor reporting including age, BMI, ICU stay, cardiac arrest, sodium, amylase, lipase, (nor)adrenaline and dobuta-/dopamine are calculated, providing a P-PASS score between nine and 27 for each donor. Study 4 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.

7.2.5.1 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

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

7.2.6 AB0 blood group rules

AB0-incompatible pancreas transplants are not allowed.

7.2.6.1 ACO-recipients (international),

AB0- compatible

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	A, B, AB and O

7.2.6.2 SU-recipients (non-German donors)

AB0-compatible

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	O, A, B, AB

7.2.6.3 Elective recipients (non-German donors)

TPG-compatible

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	O

7.2.6.4 SU recipients (German donors)

First ABO identical

Donor blood group	Eligible recipients
A	A
B	B
AB	AB
O	O

Then ABO compatible

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	O, A, B, AB

7.2.6.5 Elective recipients (German donors)

First national ABO identical

Donor blood group	Eligible recipients
A	A
B	B
AB	AB
O	O

Then national ABO compatible

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	O, A, B, AB

Then TPG compatible international

Donor blood group	Eligible recipients
A	A and AB
B	B and AB
AB	AB
O	O

7.2.7 Deviant national regulations

7.2.7.1 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 recipients will receive an offer.

7.2.7.2 Germany

Islets are considered in Germany as tissue, therefore the German pancreas donors with age > 50 years and/or BMI \geq 30 are not offered for islet transplantation. They will be allocated as extended criteria donors by vascularized pancreas rescue allocation (after offering to ACO or SU recipients) (see 7.3.2 German donor).

Non German islet-donors will not be offered to German recipients.

7.2.7.3 The Netherlands

The maximum age limit of a Dutch vascularized pancreas donor is 60 years, therefore all Dutch donors \leq 60 years are allocated as vascularized pancreas donors. Non-Dutch vascularized pancreas recipients will be offered depending on donor age profile.

7.3 EPAS – Allocation Algorithms

EPAS - allocation algorithms

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

Patients 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 www.eurotransplant.org.

Pancreas only and pancreas kidney patients have equal access to donor organs.

Allocation for vascularized pancreas transplantation is primarily patient-oriented.

Allocation to islet or β -cell transplant programs is center-oriented in BBPTP, AIBTP and NLBTP, in all other centers the allocation is recipient oriented. The quantity and quality of islets after processing is a better parameter for the selection of an islet or β -cell transplant candidate.

7.3.1 Vascularized pancreas allocation

7.3.1.1 Vascularized pancreas allocation non-German countries

Donor ≥ 5 and ≤ 50 years (or ≤ 60 in case of a donor from the Netherlands) and BMI < 30

First, to international SU vascularized pancreas recipients
(if HLA known at time of match then recipients selected by the AM match with positive advise first)

(if ≥ 1 SU patient, they appear in order of waiting time in SU)

then, to elective (T) vascularized pancreas recipients in the donor country
ranked by waiting time and region points

(if HLA known at time of match then recipients selected by the AM match with positive advise first)

then, to elective (T) vascularized pancreas recipients in other ET countries
ranked by WT and exchange balance.

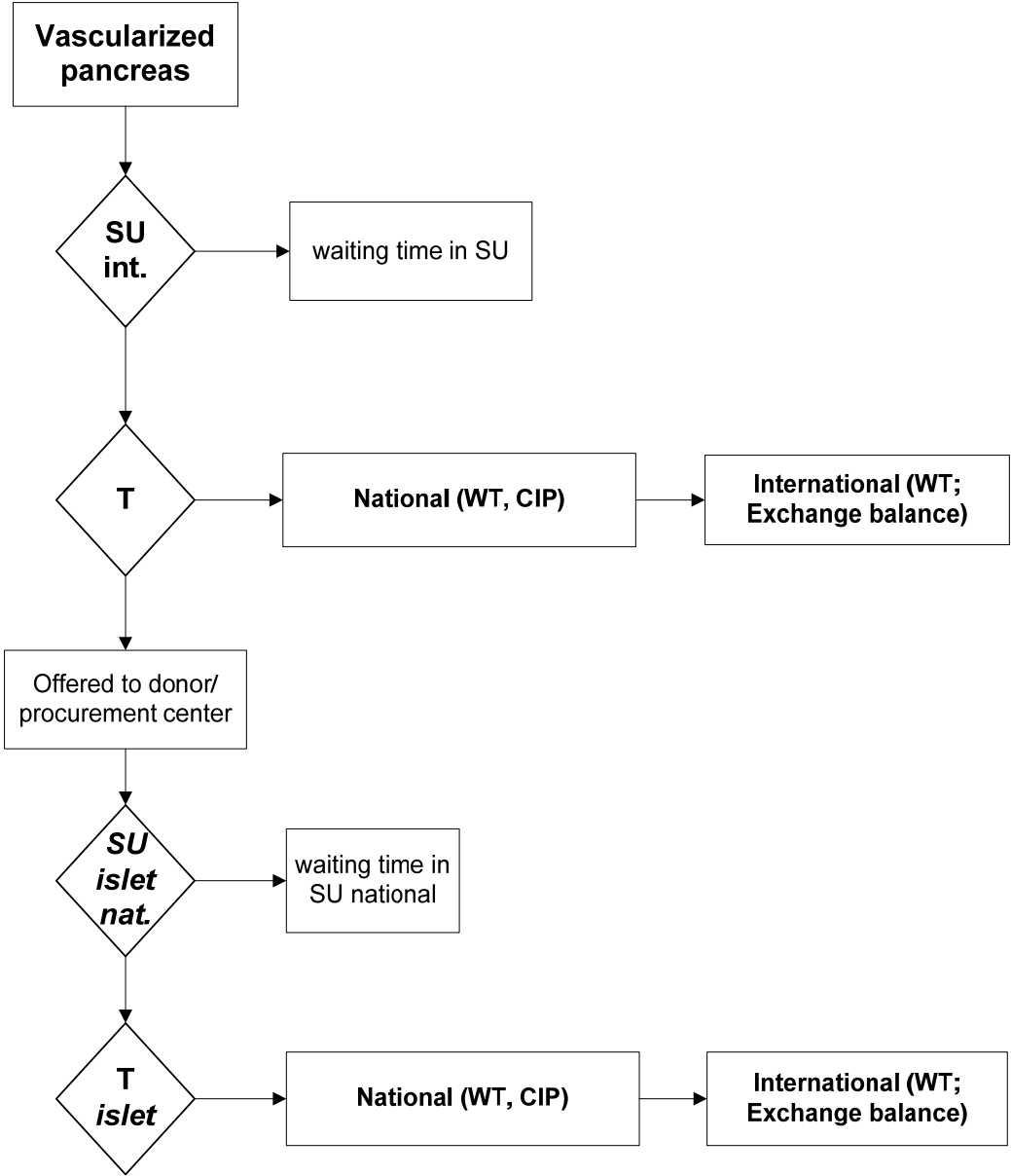
then, offered to donor/procurement center

then, to national SU islet recipient
(if ≥ 1 national SU patient, they appear in order of waiting time in SU)

then, to elective (T) islet recipients in the donor country
ranked by waiting time and region points

then, to elective (T) islet recipients in other ET countries
ranked by WT and exchange balance.
Amongst these recipients foreign SU islets recipients will appear according to T status ranking.

7.3.1.1.1 Flowchart 1 Vascularized pancreas allocation non-German countries

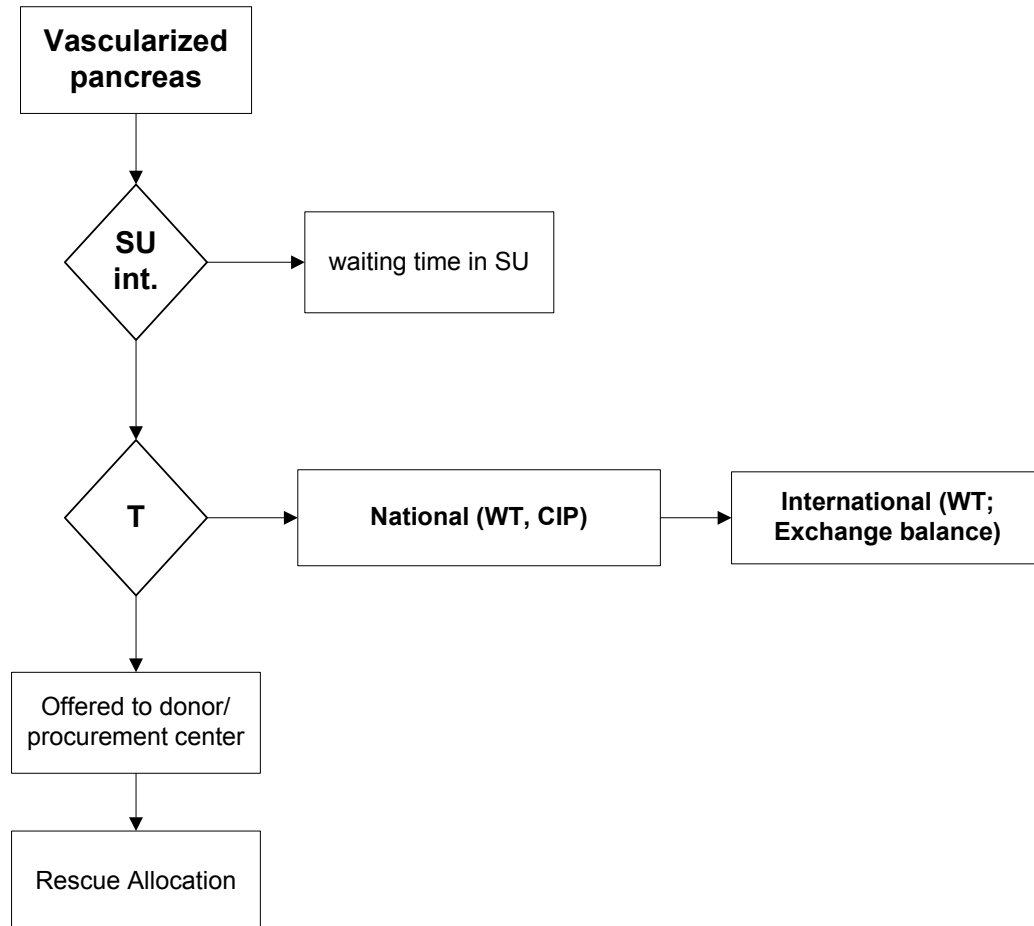


7.3.1.2 Vascularized pancreas allocation Germany

Donor ≥ 5 and ≤ 50 years and BMI < 30 in Germany

- First, to international SU vascularized pancreas recipients
(if HLA known at time of match then recipients selected by the AM match with positive advise first)
(if ≥ 1 SU patient, they appear in order of waiting time in SU)
- then, to German elective (T) vascularized pancreas recipients
ranked by waiting time and region points
(first to recipients participating in the AM program who appear on pancreas match list if HLA known)
- then, to elective (T) vascularised pancreas recipients in non German countries
ranked by waiting time and exchange balance
- then, offered to donor/procurement center
- then, rescue allocation in sequence of the match list, starting regionally. See Chapter 3 Allocation General

7.3.1.2.1 **Flowchart 2 Vascularized pancreas allocation German donor ≥ 5 and ≤ 50 years and BMI < 30**

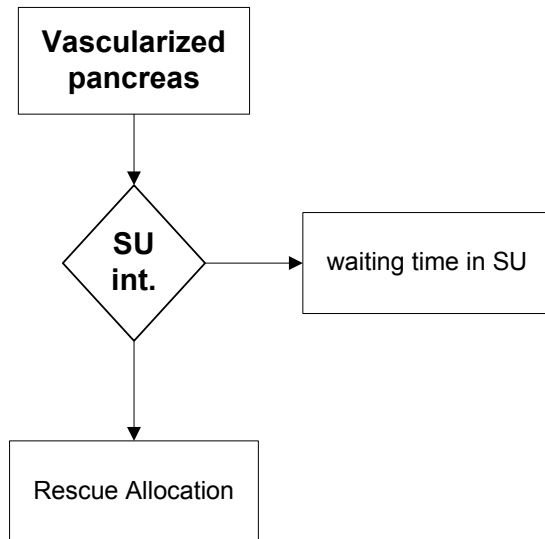


Donor ≥ 5 and ≤ 50 and BMI > 30 ; or > 50 years in Germany

First, to SU vascularized pancreas recipients
(if HLA known at time of match then recipients selected by the AM match with positive advise first)
(if ≥ 1 SU patient, they appear in order of waiting time in SU)

then, rescue allocation within the region of the donor. See Chapter 3 Allocation General

7.3.1.2.2 **Flowchart 3 Vascularized pancreas allocation German donor ≥ 5 and ≤ 50 and BMI > 30 ; or > 50 years**



7.3.2 Pancreas islet allocation

Non-German donors: Donor ≥ 5 and ≤ 50 (or ≤ 60 with Dutch donor) and BMI ≥ 30 ; or > 50 and ≤ 65 years (or > 60 and ≤ 75 years with Dutch donor)

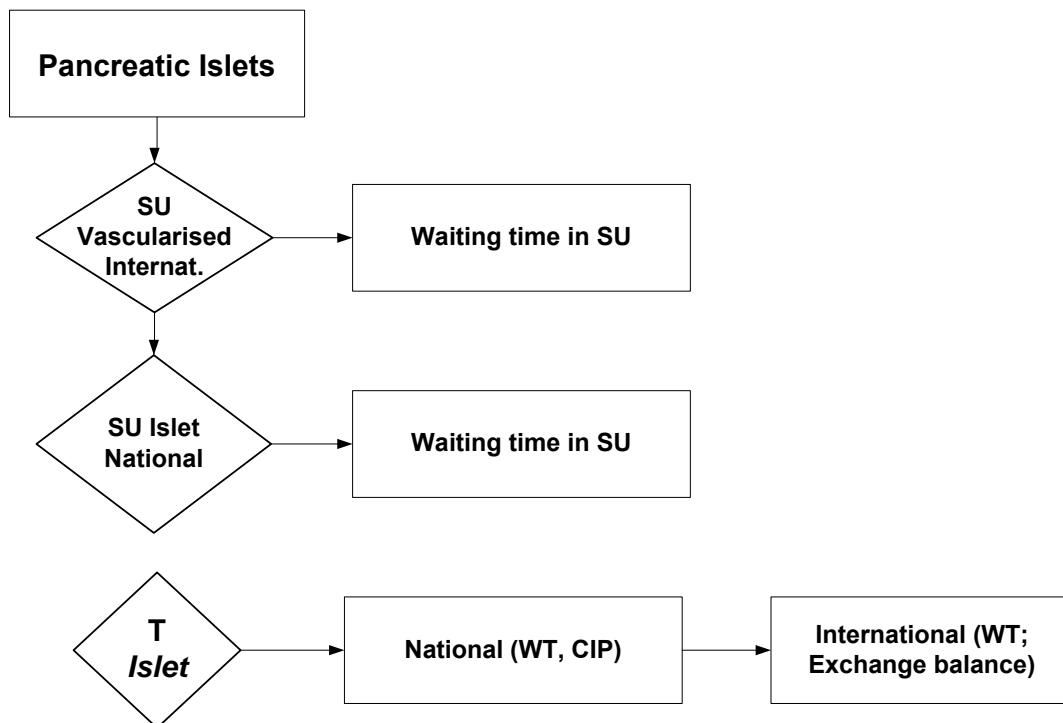
first, to international SU vascularized pancreas recipients

then, to national SU islet recipients
(if ≥ 1 SU patient, they appear in order of waiting time in SU)

then, to elective (T) islet recipients in the donor country
ranked by waiting time and region points.
Amongst these recipients foreign SU islets recipients will appear according to T status ranking.

then, to elective (T) islet recipients in other ET countries (except in Germany)
ranked by WT and exchange balance.

7.3.2.1.1 Flowchart 2 – Pancreatic islet allocation (non-German countries)



7.3.3 Non heart beating donor allocation

The Netherlands have a non heart beating vascularized pancreas transplantation program, and a non heart beating pancreatic islets transplantation program. Belgium and Luxembourg have a non heart beating pancreatic islets transplantation program. The other Eurotransplant countries do not perform non heart beating vascularized pancreas or islets transplantation.

7.4 Forms

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

7.5 Appendix 1

7.5.1 National SU islet criteria

7.5.1.1 *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.

7.5.1.2 *Other countries*

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