Chapter 2

The Recipient

Change record

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2.1 Post-mortem organ transplantation

2.1.1 Mandatory prospective listing

Patients are listed prospectively, i.e. prior to the transplantation, on an ET waiting list awaiting a single or multi-organ post-mortem donor (re)transplant. Patients listed for a post-mortem organ transplant are not excluded from transplantation with an organ from a living donor.

ET does not apply official listing criteria. The physician in charge in the transplant program has the responsibility that the patient's indication for a post-mortem organ transplantation is in accordance with current national guidelines.

2.1.1.1 Deviant national agreements

2.1.1.1.1 Germany

All patients awaiting either a post-mortem or a living donor organ transplantation must be registered prospectively on an ET waiting list[1].

2.1.1.2 Organ specific requirements

2.1.1.2.1 Pancreas

A patient on the pancreas waiting list must be diagnosed with Diabetes mellitus type I or a pancreas deficiency. Doubtful cases can be submitted to ET for evaluation by the ET Pancreas Advisory Committee (EPAC).

2.1.2 Registration procedure

The following items in the registration procedure are mandatory to assign a patient his/her unique ET number:

- date of registration;
- registering transplant center;
- last and first name (in married women also the maiden name);
- date of birth;
- gender;
- address, postcode and city;
- country of residency;
- nationality
- BSN (only for the Netherlands)
- insurance company and number (Germany and Netherlands only);
- physician's declaration that the patient was informed about :
- Eurotransplant,
- policies on waiting list management and organ allocation,
- the fact that administrative and medical data are forwarded to ET before and after a transplantation.

[1] Richtlinien zur Organtransplantation gemäß §16 TPG, published by the Bundesärztekammer (www.baek.de).

For further information, please refer to the ENIS manual (Chapter 3) in the Library of the member's area at www.eurotransplant.org.

Before completing the registration procedure, the user must confirm that the patient was informed on all aspects according to national legislation and common standards.

The patient's data in ENIS must, at all times, correspond with his/her current clinical status.

2.1.2.1 Registration outside office hours

Outside office hours, non-renal patients will only be registered by the ET duty desk if a patient is granted the high urgent status (HU). All other patients must be registered by the individual transplant center.

2.1.3 Waiting list management

2.1.3.1 Waiting list urgency code

To have the patient placed on an ET waiting list after the initial registration procedure, one or more organs must be selected together with an active urgency, i.e. any urgency other than 'temporarily not-transplantable' (NT). Only in an active urgency will a patient be selected in a match procedure from a suitable post-mortem donor. Patients in NT are not selected. For further information, please refer to the ENIS manual at www.eurotransplant.org.

Urgency codes can vary between organs. Please refer to the organ-specific chapters elsewhere in this manual.
Heart and/or lung ET Manual CH06
Liver ET Manual CH05
Kidney ET Manual CH04
Pancreas ET Manual CH07

2.1.3.1.1 High Urgent (HU)/Special Urgency (SU)

A HU/SU status for a transplant candidate must be requested by the transplant center through the corresponding organ-specific form. The form has to be completed on all items and then be sent to the ET duty desk. The form is either evaluated by the ET medical staff, members from organ-specific advisory committee or an (inter)national audit group. Only upon approval by either of these will the higher allocation priority be granted and changed in ENIS by the ET duty desk.

All forms are available in section Forms of the Library of the member's area at www.eurotransplant.org.

2.1.3.2 Listing for a multi-organ transplantation

A patient can be listed on the waiting list for more than one organ. If a patient is already listed for one organ, only the waiting list procedure for the other organ(s) is required. It is not necessary to repeat the initial registration procedure. For further information, please refer to the ENIS manual at www.eurotransplant.org.

2.1.3.2.1 Approved Combined Organ (CO)

A higher allocation priority, below HU and prior to elective (T), can be requested for multi-organ transplantations including at least two different non-renal organs, for heart-lung transplantation no ACO status can be requested, for this combination special allocation rules apply (s. chapter 06).

For further information, please refer to the organ-specific chapters elsewhere in this manual.
Heart and/or lung ET Manual CH06
Liver ET Manual CH05
Kidney ET Manual CH04
Pancreas ET Manual CH07

2.1.3.3 ENIS donor profile

2.1.3.3.1 Center-specific donor profile

A transplant center can indicate a center-specific profile that is automatically applied to all the center's patients registered on an ET waiting list at the time of a match selection from a donor.

For further information, please refer to the ENIS manual (chapter 7 in the Library of the member's area at www.eurotransplant.org.

2.1.3.3.2 Recipient-specific donor profile

A transplant center can, in addition to the center-specific profile, enter a recipient-specific donor profile that is applicable only for this particular patient. In case a recipient-specific donor profile is present at the time of a match selection, then this profile has priority over the center-specific profile.

For further information, please refer to the ENIS manual (chapter 3) in the Library of the member's area at www.eurotransplant.org.

2.1.3.4 Clinical data

Results from clinical tests in the recipient, e.g. virology, immunology or histocompatibility, should be updated immediately in ENIS. For further information, please refer to the ENIS manual at www.eurotransplant.org.

If an HIV infection is confirmed, then the patient should be placed in urgency NT (temporarily not transplantable) until a thorough case evaluation has been performed.

2.1.3.5 Death on the waiting list

If a patient dies while listed on an ET waiting list, then the date and cause of death must be entered in ENIS within 72 hours after notice to the transplant center. For further information, please refer to the ENIS manual (chapter 3) in the Library of the member's area at www.eurotransplant.org.

Timely updates in ENIS are important in order to exclude this transplant candidate from future matching procedures, thus avoiding unnecessary offers.

2.1.3.6 Removal from the waiting list

If a patient is removed from an ET waiting list for reasons other than death or transplantation, then the date and cause of the removal must be entered in ENIS within 72 hours after the removal. For further information, please refer to the ENIS manual (chapter 3) in the Library of the member's area at www.eurotransplant.org.

Timely updates in ENIS are important in order to exclude this transplant candidate from future matching procedures, thus avoiding unnecessary offers.

All accumulated waiting time is deleted.

2.1.3.7 Transplant registration

After a patient is transplanted, the transplantation must be registered in ENIS, including date and time of the transplantation. For further information, please refer to chapters 2.1.9 and 2.2.3 in this manual and the ENIS manual (chapter 6) in the Library of the member's area at www.eurotransplant.org.

2.1.3.8 Registration by ET duty desk

The ET duty desk will only list patients on, or remove patients from an ET waiting list, if it concerns patients that are or were in urgent need of an organ transplant, i.e. High Urgent (HU).

In case of removal, information on the date and cause for removal must be sent to the ET duty desk in writing.

In all other cases, registrations or removals must be performed by the transplant center itself.

2.1.3.9 Transfer of a patient

If a patient needs to be transferred to another ET transplant center, one of the centers must contact the ET medical administration by fax (see Forms at www.eurotransplant.org).

All accumulated waiting time is retained after the transfer.

2.1.3.10 Registration for a re-transplant and after removal

If a patient is registered for a re-transplant or after removal from the waiting list for reasons other than death, only the waiting list procedure is required. It is not necessary to repeat the initial registration procedure. Date and cause of failure of the previous transplant(s) must be entered in ENIS. If the patient was transplanted in a different center, then the new center will take over the follow-up of the previous transplant(s).

For further information, please refer to the ENIS manual (chapter 3) in the Library of the member's area at www.eurotransplant.org.

2.1.4 Financial aspects

2.1.4.1 First Transplantation

Any patient registered on an ET waiting list for an organ transplantation will generate an invoice.

2.1.4.2 Re-transplantation

If the patient is registered for a re-transplant, a new invoice is generated.

2.1.4.3 After removal

If the patient has been removed from an ET waiting list for other reasons than death or transplantation, and is then registered again on a waiting list, with no organ transplantation in between, then no new invoice will be generated.

2.1.4.4 Multi-organ transplantation

If the patient is registered for a multi-organ transplantation, an invoice is only generated for one organ.

2.1.4.5 Consecutive transplantation with a different organ

If a patient received a transplant and is later registered on an ET waiting list for an organ other than the one transplanted, then an invoice is generated for this new organ.

2.1.4.6 Living donor organ transplantation

If a patient is registered on an ET waiting list for a post-mortem organ transplantation, and is then transplanted with an organ from a living donor, then the registration fee is not reimbursed.

2.1.4.7 Deviant national agreements

The invoice is sent to the	**in**
transplant center at time of registration	Austria, Belgium, Luxembourg, Slovenia
patient or his/her insurance company. Therefore, a patient's insurance company and insurance number are mandatory upon registration on the waiting list	Germany
Nederlandse Transplantatie Stichting (NTS)	The Netherlands
Ministry of Health and Social Welfare	Croatia

2.1.5 Non-resident patients

2.1.5.1 Definition of RESIDENT

Eurotransplant defines patients as 'RESIDENT' when the patient:

- Carries the nationality of an ET country or
- Legitimately lives or works in an ET country for a longer period than 6 months or
- If the patient is defined as such according to the national legislation of the country where the patient is listed.

Other patients are considered as non-resident patients; the 5% rule, as mentioned in 2.1.5.4, is applicable for this category of patients

Before registering a non-resident patient, a transplant center has to make sure that organizational and financial matters are settled and that the necessary follow-up is guaranteed.

2.1.5.2 Standard exception

The resident status is automatically assigned to a non-resident patient at the time of registration if he/she:

- lives and is treated in either of the two Italian regions Trentino or Alto-Adige, and is listed at the transplant center Innsbruck, Austria, or
- In the event that there is an active twinning agreement (approved by the Board of ET) between an ET center with a center or country outside ET, patients from this twinning center / country outside ET with the nationality of that country are counted as residents

2.1.5.3 Verification of residency status

The residency status is verified by:

- passport or
- official document of residency or
- working permit or
- citizenship applicable in ET countries where citizenship is considered to be equal with residency
- rule specified by the national authority

2.1.5.4 5% rule - Liver and thoracic organs

The number of non-resident registrations for patients (either first or repeat) for a thoracic or liver (re)transplant should not exceed 5% of the total number of post-mortem transplantations (either first or repeat) by this center in the preceding year.

2.1.5.4.1 Addendum thoracic organs

Due to the short acceptable cold ischemia time (CIP), a transplant center has to guarantee that the non-resident patient can be in the center within 4 hours (heart) or 6 hours (lung), respectively.

2.1.5.4.2 Monitoring of 5%-rule

The 5%-rule is checked on a monthly basis by the ET administration. Centers approaching the 5% receive an official warning in writing. Centers exceeding the 5% will be notified to the ET Board.

2.1.5.5 Kidney, Pancreas and Intestine

Non-resident patients are not allowed to be registered for a post-mortem transplantation on the ET kidney, pancreas and intestine waiting list, respectively.

2.1.5.6 Living donor transplantation in non-residents

- Living donor transplantation in non-residents are not included in the calculation of the 5% rule.
- ET is not responsible for living donor selection. The responsibility for the complete living donor procedure is at the transplant center
- Living donor transplantation with non-ET residents should comply with the existing ET recommendation (REC01.06)
- Non-residents living donors evolving to a state of terminal organ failure are eligible for listing within the 5 % rule.

2.1.5.7 Deviant national regulations

2.1.5.7.1 Belgium

According to the 'Royal Decree regarding the procurement and allocation of human organs' (November 24, 1997), a non-resident person is defined as a person who has a nationality different from the Belgian, or one of the other ET countries, and/or who has no permanent address in Belgium, or one of the other ET countries.

Non-residents can only be listed on a Belgian organ-specific waiting list after approval of the Belgium ministry.

2.1.6 The HIV positive recipient

Prior to registration, potential recipients should be tested for Human Immunodeficiency Virus (HIV) antibodies according to Good Laboratory Practice. In case of a positive test result, he/she can be considered for organ transplantation, following a careful case by case evaluation.

2.1.7 Registration in more than one transplant center

2.1.7.1 Within ET

It is prohibited to register a patient simultaneously at two or more different transplant centers within the ET countries.

2.1.7.2 Outside ET

It is prohibited to register a patient simultaneously at one transplant center within the ET countries and at one or more centers outside the ET countries.

2.1.8 Non-approved transplant centers

A transplant center must not list a patient on an ET waiting list if the center has no official approval by the competent national health authority allowing organ transplantations. Already registered patients must be transferred to an approved transplant center.

In case of force majeure, a transplant center must immediately contact the ET medical staff prior to any allocation and/or transplantation. The problem will be discussed with the chairman of the respective ET Advisory Committee, the ET medical director and/or the president of ET.

2.1.9 Registration of a transplantation

A transplant center must register organ transplantation in ENIS as soon as possible but no later than 72 hours after the transplantation. The registration of this transplantation (code T1, T2 or T3) will remove the patient from the ET waiting list and assign the Follow-up code (FU).

In case of a re-transplantation, cause and date of graft failure of the previous transplantation must be entered in ENIS. Follow-up data can be entered directly in ENIS at any time. For further information, please refer to the ENIS manual at www.eurotransplant.org.

2.1.10 Follow-up

A transplant center must enter follow-up information in ENIS for transplantations performed either in this center or for recipients transplanted elsewhere and transferred to this center. For further information, please refer to the ENIS manual (chapter 6) in the Library of the member's area at www.eurotransplant.org.

2.1.10.1 Immediate follow-up

The following data is asked in ENIS:

- Cold Ischemia Period (CIP): time between start of perfusion and moment the organ is kept at >4ºC (during transplantation or its immediate preparation);
- Second Warm Ischemia Period (or anastomosis time): time between end of CIP and complete re-vascularization;
- Initial graft function;
- Immunosuppressive regimen (induction therapy);
- Transplant technique.

2.1.10.2 Long-term follow-up

The following data is asked in ENIS:

- Graft function at 1 week, 1m, 3m, 6m, and once a year thereafter (or as of date recipient last seen) post-transplant;
- Maintenance and updates of immunosuppressive agents;
- Date(s) of graft rejection, histological confirmation of rejection, anti-rejection therapy;
- Date and cause of graft failure or death (if applicable);
- Date the recipient was last seen or was lost to follow-up.

2.1.10.3 Liver

2.1.10.3.1 HU Liver Study

The ET medical administration sends questionnaires for transplantations performed in urgency HU. The data requested comprises the pathological report of the explanted liver and graft and recipient status (1m, 3m, 6m and 12m post-transplant).

2.1.10.3.2 Liver transplants since 01.01.2006

All liver transplants since 01.01.2006, except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the liver follow-up procedure can be found in the Library of the member's area at www.eurotransplant.org.

2.1.10.4 Kidney

2.1.10.4.1 Kidney transplants since 01.01.2006

All kidney transplants since 01.01.2006, except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the kidney follow-up procedure can be found in the Library of the member's area at www.eurotransplant.org.

2.1.10.5 Heart

All heart transplants except those performed in Dutch transplant centers, are integrated into ENIS.

The detailed description of the follow-up procedure 'Heart post-transplant follow-up package' can be found in the Library of the member's area at www.eurotransplant.org.

2.1.10.5.1 Dutch thoracic transplants

All thoracic transplants performed in the Netherlands are integrated into the NOTR.

The detailed description of the follow-up procedure 'Heart post-transplant follow-up package' can be found in the Library of the member's area at www.eurotransplant.org.

2.1.11 Submission of data to international registries

Transplant-related data are submitted to (inter)national research registries in the field of organ transplantation with consent by the transplant center.

2.1.11.1 European Liver Transplant Registry (ELTR)

On request of a transplant centers, ET will send their follow-up data to the ELTR (www.eltr.org), written consent is necessary.

2.1.11.2 International Society for Heart & Lung Transplantation (ISHLT) Registry

Follow-up data for thoracic transplantations are forwarded to the ISHLT (www.ishlt.org).

2.1.11.3 International Pancreas Transplantation Registry (IPTR)

Follow-up data from pancreas transplantations are forwarded to the IPTR (www.iptr.umn.edu).

2.1.11.4 Collaborative Transplant Study (CTS)

ET and CTS (www.ctstransplant.org) exchange data on all organ transplants performed within ET, written consent by the individual center is necessary.

2.1.11.5 MrQ Heart

The clinical profile of all transplant candidates listed on the heart waiting list is integral part of ENIS since October 23, 2003. A patient's profile is entered at time of initial registration and, from then on, at regular intervals. Evaluation is terminated either at time of heart transplant, or at time of removal from the waiting list for reasons other than heart transplant.

The detailed description of the registration procedure 'Heart waiting list monitoring package' can be found in the Library of the member's area at www.eurotransplant.org.

2.1.11.6 Nederlandse Orgaan Transplantatie Registratie (NOTR)

Dutch transplant centers send all data on transplantations to the central database of the NOTR. The NOTR collects and manages the data and transfers it to ENIS and e.g. (international) transplant registries or governmental institutions.

2.1.11.7 Austrian kidney transplantations

Dr Kramar (Linz) collects all follow-up data for kidney transplantations performed in Austria (except Vienna) and transfers the data to Eurotransplant.

This database is planned to be integrated into ENIS. Further details will be provided in the future.

2.1.12 Virological screening after transplantation

Eurotransplant recommends performing at least at 3 and 12 months post-transplant a screening for HIV, Hepatitis B and Hepatitis C.

2.1.13 Donor-related disease transmission

If a transplant center suspects or has evidence for a donor-related disease transmission (infection, malignancy etc.), the center should immediately inform the ET medical staff in writing.

The ET medical staff will subsequently evaluate the case together with the donor

center and will contact the other transplant centers that received either organs or tissues from this donor.

The transplant centers contacted are responsible to inform their recipients transplanted with either organs or tissues from this donor and to take appropriate measures.

2.1.14 Data release

An individual or organization can request in writing (English) donor or recipient-related data.

The ET Medical Staff reviews the request and, after approval, contacts the center(s) involved. The following information is forwarded without revealing a recipient's identity:

- ET number, gender, age, primary disease and waiting time;
- transplant program;
- initial graft function.

This data release is covered by the physician's declaration at the time of listing the patient on an ET waiting list.

2.1.15 Data privacy

A transplant center must adhere to the current national legislation on privacy and protection of personalized data when releasing data about patients.

2.1.16 Use of organs for other than transplantation

2.1.16.1 Discard

If an organ is not-transplantable, at time of procurement or upon arrival in the transplant center, respectively, the involved team must immediately contact the ET duty officers.

The discard of an organ(s) is discussed with the donor procurement organization or center and the transplant program(s) involved. Following this it is decided where the organ will ultimately be discarded. ET documents the location of the discarded organ.

2.1.16.2 Research

If a procured organ is not transplantable, it can be offered to an ET transplant research program whose project has been approved by an ET Advisory Committee and by the ET Board. Consent from the donor through the donor procurement organization or center is obligatory. ET documents the location of the research program.

For further information, please refer to the organ-specific chapters in this manual.

2.1.16.2.1 Pancreas

Islet transplant programs and pancreas research programs should keep a record of all accepted donor pancreata, as well as the ultimate disposition (research, discard, transplantation, bank).

This information should be sent to the secretary of the Pancreas Advisory Committee on a quarterly basis.

2.1.17 Violation of allocation rules

Violations of current allocation rules are reported by ET to the director of the transplant center involved, the chairperson of the national transplant society and the chairperson of the respective ET Advisory Committee.

The transplant center is asked to respond to this letter in due time explaining the reasons for the non-compliance.

Violations are further discussed during the ET Advisory Committee meetings.

2.1.17.1 Deviant national agreements

2.1.17.1.1 Germany

A copy of violation letters is sent to the chairperson of the Prüfungskommission of the Bundesärztekammer (BÄK).

2.1.17.1.2 The Netherlands

A copy of violation letters is sent to the Head of Medical Affairs of the Nederlandse Transplantatie Stichting (NTS).

2.1.17.1.3 Belgium

A copy of violation letters is sent to the chairperson of the Belgische Transplantatie Raad (BTR).

2.1.17.1.4 Croatia

A copy of violation letters is sent to the Ministry of Health and Social Welfare.

2.2 Living donor organ transplantation

Patients listed on one or more of the ET waiting lists awaiting a living donor organ transplant are not excluded from a single or multi-organ transplant from a post-mortem donor.

It is the sole responsibility of a transplant surgeon and/or physician to prepare a living donor transplant, i.e. donor screening and patient selection. The selection of living organ donors should follow the guidelines of the ET Ethics Committee, the European Society for Organ Transplantation (ESOT), the International Society for Organ Transplantation (ISOT), the Council of Europe as well as current national guidelines and/or laws on transplantation.

2.2.1 Domino organ transplantation

If a post-mortem donor organ is transplanted to a patient whose primary disease allows the use of his/her therapeutically explanted organ for a consecutive second transplant, then this patient is called a domino donor. A domino donor can be considered a living donor if this is in accordance with current national laws on transplantation and/or guidelines.

2.2.1.1 Domino heart

A domino heart donation exclusively occurs after combined post-mortem heart+lung transplants. This healthy heart can be used for a consecutive transplantation in a recipient who is chosen from the center's own waiting list. If no suitable recipient is available, then this organ is reported back to the ET duty desk for patient-specific allocation. (ch06 page…..)

2.2.1.2 Domino liver

A domino liver donation e.g. occurs in a patient who is suffering from a non-cirrhotic metabolic liver disorder, e.g. Familial Amyloid Polyneuropathy (FAP) or Oxalosis. This compromised liver can be used for a consecutive transplantation in a recipient who is chosen from the center's own waiting list. If no suitable recipient is available, then this organ is reported back to the ET duty desk for patient-specific allocation.

The genetic enzyme defect of the liver will only become clinically apparent in a second recipient long after the transplantation. Therefore, patients e.g. with a reduced life expectancy can be chosen as a recipient for such a liver, as the expected time until development of clinical signs resulting from the compromised liver organ might extend beyond the expected life expectancy of the recipient. Ch05 page….)

2.2.1.3 Domino transplantation in Germany

Transplant candidates willing to accept a domino liver or heart must be indicated as such in the patient-specific donor profile in ENIS. They will then be allocated through to the modified allocation algorithm in accordance with the 'Richtlinien zur Organtransplantation gemäß §16 TPG' (www.baek.de).

2.2.2 Registration and waiting list

A patient can be listed on an ET waiting list, clearly indicating that he/she is exclusively awaiting a living donor organ transplant.

The registration procedures in ENIS are identical to those for patients awaiting a post-mortem organ transplant.

Upon registration, option 'Yes' for 'Family transplant' can be chosen. If 'Yes' is chosen, then this patient is excluded from any selection in a match procedure for a post-mortem donor organ.

2.2.2.1 Financial aspects

If 'Yes' is indicated for 'Family transplant' at the time of the patient's registration on an ET waiting list:

no invoice is generated in	Austria, Belgium, Luxembourg, The Netherlands, Slovenia
an invoice is generated in	Germany

If the patient has first been registered on an ET waiting list for a post-mortem organ transplant, and is later registered for a living donor transplant by indicating 'Yes' for 'Family transplant', then the registration fee will not be returned.

If the patient has first been registered on an ET waiting list for a living donor transplant and is later indicated for post-mortem donor organ transplantation by changing 'Family transplant' to 'No' to register the patient for a post-mortem organ transplantation only, then an invoice is generated. The transplant program must then provide all mandatory data necessary for the registration and allocation procedure for the post-mortem organ match programs.

It is recommended to register both the living donor organ transplantation and the living donor at the same time.

2.2.2.2 Deviant national agreements

2.2.2.2.1 Germany

German transplant centers cannot indicate 'Family transplant', as all transplant candidates awaiting a post-mortem and a living donor organ transplant must prospectively be registered on a post-mortem ET waiting list in an active urgency.

All transplant candidates awaiting a living donor liver transplant are thus given the chance to receive a post-mortem organ before a living donor organ transplant.

2.2.3 Registration of a transplantation

A transplant center must register an organ transplantation in ENIS as soon as possible but no later than 72 hours after the transplantation The registration of this transplantation (code T1, T2 or T3) will remove the patient from the ET waiting list and assign the Follow-up code (FU).

In case of a re-transplantation, cause and date of graft failure of the previous

transplantation must be entered in ENIS. Follow-up data can be entered directly in ENIS at any time. For further information, please refer to the ENIS manual at www.eurotransplant.org.

Numbers for living donor transplants are added up to a center's post-mortem transplant activity, in order to assign the correct number of votes for the center's delegates in the annual Assembly Meeting (see ET Articles of Association).

2.2.3.1 Domino transplantation

In case of a domino procedure, the ET duty officers should be contacted to register the recipient of the post-mortem organ as the subsequent domino donor. In case the donor center does not have a recipient ET will generate a match list. The transplant resulting from the domino procedure is registered by the domino transplant center itself.

2.3 Forms

All forms can be found in section Forms of the Library of the member's area at www.eurotransplant.org.