Introduction

This Newsletter contains the usual items such as statistics, calendar of events, the reports of the last Board meeting and Advisory Committee meetings including approved recommendations. Besides these items you will find the Presidential Address and the reports by the general and the medical director given at the recent annual Eurotransplant meeting. Further issues addressed in this Newsletter are the report of the Assembly and of the EuroTransplant Coordinators Workshop as well as news from the duty desk. The latter concerns broadened travel regulations to Croatia and implementation of several recommendations.

We hope you will enjoy reading this Newsletter!

Arie Oosterlee
General Director

Announcement

CHANGED DATE

The 2011 Eurotransplant annual Meeting
will take place
October 13 – 14, 2011
in Leiden, the Netherlands
### NUMBER OF ORGANS FROM DECEASED DONORS USED FOR TRANSPLANTATION

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<th>Croatia</th>
<th>Germany</th>
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<th>Netherlands</th>
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### NUMBER OF TRANSPLANTS PERFORMED

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## Calendar of Events

### 3rd Belgian Meeting on Transplantation of Organs from Non-Heart-Beating Donors
(Donation after Cardiac Death)
November 25, 2010
Brussels, Belgium
For information: http://uclmontgodinne.be (click on “Congrès”)
Phone: +32 8142 3021
E-mail: uss@uclouvain.be

### 2010 Consensus Conference on Liver Transplantation for HCC
December 2 – 4, 2010
Zürich, Switzerland
Congress Office: Ms. Madeleine Meyer
University Hospital Zurich, Dept. of Visceral and Transplantation Surgery
Raemistrasse 100
8091 Zurich, Switzerland
Phone: +41 (0)44 255 2300
E-mail: madeleine.meyer@usz.ch
For information: www.OLT4HCC.org

### Eurotransplant Annual Winter Meeting 2011
January 26 – 28, 2011
Alpbach, Austria
For information: Mrs. Ellen Houwaart
Eurotransplant, P.O. Box 2304
2301 CH Leiden, the Netherlands
Ph: +31 71 5795795; Fax: +31 71 5790057
E-mail: e.houwaart@eurotransplant.org
For information: www.eurotransplant.org

### World Congress of Nephrology
April 8 – 12, 2011
Vancouver, BC, Canada
For information: www.wcn2011.org

### 31st Annual Meeting and Scientific Sessions of the International Society for Heart & Lung Transplantation (ISHLT)
April 13-16, 2011
San Diego, CA, USA
For information: isHLT@isHLT.org

### American Transplant Congress
April 30 – May 4, 2011
Philadelphia, PA, USA
For information: www.atcmeeting.org

### 25th European Immunogenetics & Histocompatibility Meeting (EFI)
May 4 – 7, 2011
Prague, Czech Republic
For information: www.efi2011.eu

### 13th World Congress of International Pancreas and Islet Transplant Association (IPITA)
June 1 – 4, 2011
Prague, Czech Republic
For information: www.ipita2011.org

### International Congress of International Liver Transplantation Society (ILTS)
June 22 – 25, 2011
Valencia, Spain
For information: www.ilts.org

### XLVIII Congress of European Renal Association – European Dialysis and Transplant Association (ERA-EDTA)
June 23 – 26, 2011
Prague, Czech Republic
For information: www.eraedta2011.org

### 15th Congress of the European Society for Organ Transplantation (ESOT)
September 4 – 7, 2011
Glasgow, United Kingdom
For information visit www.esot.org

### 11th Congress of the International Society for Organ Donation and Procurement (ISODP)
November 27 – 30, 2011
Buenos Aires, Argentina
For information: www.isodp2011.org.ar

### Eurotransplant Annual Meeting 2011
October 13 & 14, 2011
Leiden, the Netherlands
For information: Mrs. Marianne Franzen
Eurotransplant, P.O. Box 2304
2301 CH Leiden, the Netherlands
Ph: +31 71 5795795; Fax: +31 71 5790057
E-mail: mfranzen@eurotransplant.org
www.eurotransplant.org
Summary of the meeting of the Eurotransplant International Board on Wednesday, September 22, 2010 in Leiden, the Netherlands

Ellen Houwaart, secretary to the Eurotransplant International Board

The Board was informed about the progress of the implementation of recommendations and several projects.

On July 24, 2010 a round table meeting on the subject of the EU Directive on standards of quality and safety of human organs intended for transplantation took place in presence of the EU Commissioner for Health and Consumer Policy, Mr. John Dalli. The meeting was also attended by Mrs. Dr. Beate Berk, Bavarian State Minister for Justice, Prof. Robert Langer, Director of the Department of Transplantation and Surgery at the Semmelweis University in Budapest, Hungary, and Dr. Hans Neft, Official of the Bavarian State Ministry of the Environment and Public Health and the Board members B. A report of this meeting has been published in Newsletter 218.

A first meeting of the (future) competent authorities, as described in the above mention EU Directive, took place in Brussels on September 6 & 7, 2010. The ET President and Directors attended this meeting.

With regard to progress of the EFRETOS project, the Board was informed that the project is in a crucial phase at the moment. Several expert groups have been working on setting definitions for the datasets of the future umbrella registry. It is of the utmost importance that these datasets will be accepted by the experts in the field in the end.

The Board discussed the issue of migration of Dutch patients to Belgium in order to get transplanted there. The Board was informed that ET is working on a solution together with the Belgian Ministry of Health and the involved transplant centers.

ET is in the process of developing a new website. This project is progressing well and it is expected that the new website can be launched at the beginning of 2011.

Concerning the finances of ET, the Board was informed that the financial situation of ET has improved significantly. During the meeting the Board approved a policy on the financial reserves, which will also contribute to a stable financial situation. Furthermore, the Board approved the budget proposal for 2011.

Reports of the ET Thoracic Advisory Committee (EThAC) and the Organ Procurement Committee (OPC) were discussed. A major issue of the EThAC meeting had been the forthcoming change of the thoracic allocation system in Germany and harmonization with the ET allocation rules. This topic lead to extensive discussions in the Board but all recommendations proposed by the EThAC have been approved. Since the reports will be published in this issue of the ET Newsletter, there is no need to further elaborate on it in this summary.

The approved recommendations, which were submitted to the Board by the EThAC and the OPC are also published in this Newsletter.

The issue of housing of ET was also discussed during this meeting. Since Bio Implant Services (BIS) merged with the Netherlands Bone bank Foundation, it became a tissue bank with commercial interest (NBF-BIS). This made it impossible for ET to continue cooperation. After ample discussion it has been decided that NBF-BIS will search for new premises and move out of the building in which the foundations have shared services for so many years.

ET continues to try to establish cooperation with potential new member countries. In this regard the Board is informed that the transplantation and donation situation in Serbia improves rapidly. The donation rates have increased again. ET and Serbia will exchange ‘Letters of Intent’ to confirm the intentions of both parties to establish cooperation.

The ET President and Directors visited another potential new member state in September 2010, namely Hungary. The consultations with Hungary are promising. It is hoped that the efforts will succeed in a preliminary cooperation agreement in due time.

During their last meeting, the Board expressed the wish to give the President to the Board a more independent position unrelated to a specific organ. In this regard, the Board discussed a proposal for the amendment of the ET Articles of Association. The Board approved the amendment of article 6.6 to:

*The Board shall elect a President from the current or former members A for a period of three (3) years. If and when the Board appoints a member A as President, he renounces his capacity as member A and will with due observance of the provisions in article 6, paragraph 3 a new member A be elected from the Assembly.*

The Board also approved minor textual changes in the Articles of Association and the Basic Mandate in order to harmonize the wordings of the two documents.

Finally, the Board was informed about the applications for the Henk Schippers Young Investigators (HSYI) Award 2010. Six applications from four different countries were submitted. The members of the HSYI Award committee unanimously declared Dr. Robin Vos, Leuven, Belgium, as the winner of the 2010 HSYI Award.

The following recommendations have been discussed and approved by the Board:
### Thoracic Advisory Committee

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<th>Code</th>
<th>Description</th>
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<td>RThAC01.10</td>
<td>A pediatric recipient is a heart or heart+lung transplant candidate, who at time of listing is under the age of 16 years or proven to be in maturation. This proof has to be delivered by the transplant center by a report from a competent radiologist or pediatric endocrinologist on an X-ray of the left hand, not older than 3 months and judged upon by two independent auditors appointed by Eurotransplant. In case of a split decision, a third auditor has to be consulted for a final decision. In order to keep the pediatric status, the proof of immaturity has to be updated yearly as long as the recipient is still on the waiting list. This recommendation will be forwarded to the national authorities for authorization.</td>
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<tr>
<td>RThAC02.10</td>
<td>All pediatric heart or heart+lung transplant candidates are granted the Hu status, as soon as they are registered on the waiting list in an active urgency. This recommendation will be forwarded to the national authorities for authorization.</td>
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<tr>
<td>RThAC03.10</td>
<td>Within each tier of Hu patients the hospitalized pediatric patients will have priority over all other Hu patients. This recommendation will be forwarded to the national authorities for authorization.</td>
</tr>
<tr>
<td>RThAC04.10</td>
<td>AB0 incompatible heart or heart+lung transplantation is possible for patients under the age of 2 years, provided that: a protocol approved by the local ethics committee has been submitted by the transplant center. This recommendation will be forwarded to the national authorities for authorization.</td>
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<tr>
<td>RThAC05.10</td>
<td>The duration of Hu status for international Hu heart or heart+lung patients will be extended from 7 days to 8 weeks. If patients on Hu-status are temporarily downgraded to status T and/or NT for no longer than 28 days and are then reassigned a Hu status, their previous Hu time will be returned. This recommendation will be forwarded to the national authorities for authorization.</td>
</tr>
<tr>
<td>RThAC06.10</td>
<td>All donor hearts or heart+lung blocks reported by Germany will be allocated via the scheme described in RThAC02.05 where the following adaptations will be introduced: - Introduction of a new main rank tier, i.e. hospitalized children are ranked above other High Urgency (Hu) patients; - All children have the Hu status; - Abolishment of the Urgency (U) status; - Introduction of a new AB0 blood group tier; - AB0 blood group incompatibility will be allowed for patients under 2 years of age; - Introduction of a new sub rank tier, i.e. highly immunized patients; - Change of the rule for the sequence Hu- (T or NT) –Hu; - Extension duration Hu national from 7 days to 8 weeks; - Introduction of a new definition of a child recipient. This recommendation will be forwarded to the national authorities for authorization.</td>
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**a** RThAC02.05 (approved by the Board on January 19, 2005)

Hearts should be allocated:
- first to International Hu patients (access to foreign country list if negative Hu balance)
- then to National Hu patients and International Hu patients (access to foreign country list if negative total balance)
- then to National U patients (only in Germany)
- then to National Approved Combined Organ (ACO) patients
- then to National elective patients
- then to International Hu patients
- then to International U patients (only in Germany)
- then to International ACO patients
- then to International elective patients.

This allocation model will be evaluated one year after implementation.

The international Hu and the German Hu status are assigned according to the German Hu criteria; this status is only granted after a positive advice by the majority of international auditors. However, the national Hu status in Austria, Belgium, Slovenia and the Netherlands can be assigned by the treating physician according to national criteria.
**ORGAN PROCUREMENT COMMITTEE**

**ROPC02.10**
A. It is the responsibility of the procurement and the transplant centers to immediately report to Eurotransplant all known transmittable diseases (e.g. infection, malignancy etc.) that might originate from the donor or the donation procedure.
B. 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.
C. In a later phase Eurotransplant will inform the competent authorities about the events.

*This recommendation will be forwarded to the national authorities for information.*

**FINANCIAL COMMITTEE**

**RFC02.10**
The Financial Committee recommends the Board to approve the budget proposal 2011.

*This recommendation will be forwarded to the national authorities for information.*

**RFC03.10**
The Financial Committee recommends the Board to approve the Policy on financial reserves of ET.

*This recommendation will be forwarded to the national authorities for information.*

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**Announcement**

**The 2011 Eurotransplant winter Meeting**

will take place  
**January 26 – 28, 2011**

in Alpbach, Austria
The following reports from the Advisory Committees were discussed by the Eurotransplant International Board on September 22, 2010 in Leiden, the Netherlands.

Please note that all approved recommendations mentioned in the following reports, are published elsewhere in this Newsletter.

Report of the meeting of the Eurotransplant Thoracic Advisory Committee (EThAC)

Chairman: Prof. Dr. G. Laufer
Secretary: Dr. J. Smits

The EThAC met on Wednesday, July 7, 2010
Members present: 12 + 2 external advisors + 1 director + 1 ET co-worker
Members excused: 2

A. Proposal for a new German heart or heart+lung allocation scheme and the consequences for the other ET countries

The EThAC was informed on changes in the German heart or heart+lung allocation scheme (see RThAC06.10). In order to establish a smooth interface with the international patients, the EThAC discussed how to handle high immunized patients in other countries than Germany, the German proposal of pediatric patient definition and the sub rank tier system.

The concept to give highly immunized patients preference in allocation is considered to be attractive also for other countries. However, a formal decision to implement a similar scheme also in other countries was not taken during the meeting.

The EThAC decided to recommend a new definition of a pediatric transplant candidate, based on the definition formulated by the ETKAC (see RThAC01.10).

Next, the EThAC discussed the pros and cons of considering all pediatrics as HU transplant candidates. The discussion resulted in RThAC02.10.

Furthermore, it was agreed to introduce an additional sub rank tier in the international HU tier prioritizing hospitalized over non-hospitalized children (see RThAC03.10).

As concern exists that this regulation might result in more, maybe even unnecessary hospitalization, ET has been asked to closely monitor the corresponding developments of pediatric recipients on the waiting list.

With regard to this topic the EThAC also formulated RThAC04.10 and RThAC05.10.

B. Proposal for a new German lung allocation scheme and the consequences for the other ET countries

The EThAC was informed on the current proposal for a new German lung allocation scheme and discussed the consequences for other ET countries. The major question was how to handle international exchange between countries with a Lung Allocation Score (LAS) system and countries without this system.

The following options for integrating national patients into a LAS system would be possible:

- Replacing the HU balance by a total balance and allow HU patients with a negative balance on top of the waiting list as long as the total balance is negative.
- Replacing the HU balance by a total balance and calculate a LAS for the international patients then sort them into the national list as long as the total balance is negative.

A new scheme also has to take into account the balancing between LAS countries and placing of patients from a country with a LAS system on the waiting list of a country with the current system in case of a negative balance.

Because of the complexity of the topic no decisions were taken yet. The topic will be further discussed during the next meeting of the EThAC.

Report of the meeting of the Eurotransplant Organ Procurement Committee (OPC)

Chairman: Prof. Dr. D. Ysbaert
Secretary: C.M. Tieken, MD

The OPC met on Thursday, June 24, 2010
Members present: 10 members + 2 observers + 1 director + 1 ET co-worker
Members excused: 4 members + 2 observers

A. Donor information and allocation

The OPC discussed the legal impossibility for the Deutsche Stiftung Organtransplantation (DSO) to translate donor reports and test results in the English language as well as verbal communication problems between transplant coordinators in the different countries.
It was concluded that that two points should be aimed at in order to achieve an as optimal as possible situation:

a. motivating local doctors to provide the test results in the English language;

b. making progress in providing the test results through tick boxes.

B. Tracking and tracing of potential risk factors

With regard to tracking and tracing potential risk factors, the OPC formulated ROPC02.10.

The results of a questionnaire issued by the working group PRIandO (= Potential Risk and Discarded Organ) was discussed. One of the conclusions is that more quality control on discarded organs is necessary. In order to achieve this it will be focused on the improvement of the (electronic) quality forms. This issue will be further discussed at the next OPC meeting.

For sake of transparency, the ET office had indicated that the final destination of an organ that was explanted and shipped to a tissue bank which was initially intended for transplantation, should be known. Unfortunately, this is not possible at least for Germany, since only donor hospitals are aware of the destination of organs. For this reason it is considered to be essential to not only inform the DSO but also donor hospitals in case of potential risks.

C. Proposal for adaptation of donor reports

The OPC accepted a proposal for adaptation of donor reports. It was decided to try to synchronize the DSO and ET donor reports as much as possible, in such way that already implemented items might not have to be changed and that some new items can be added. Some already implemented items in the DSO system need to be discussed by the ET Advisory Committees involved.

D. Renewed discussion on EBV screening and discussion on BKV screening

**EBV screening (ROPC01.08)**

The OPC discussed a request from one of the ET transplant centers to have the EBV screening available prior to transplantation. Based on the data available the OPC decided not to change the current regulation regarding EBV screening:

**ROPC01.08**

a. The Epstein Barr test results might have influence on the treatment of a post transplant recipient.

b. Testing for Epstein Barr Virus in potential donors is mandatory; the test result is allowed to become available only after allocation.

c. The tests result should be forwarded to the transplant centers via Eurotransplant.

**BKV screening**

With regard to BKV screening the OPC concluded that there is no added value to test for BKV which was requested by the transplant center involved. The transplant center is free to start a study but the study will not be initiated by ET.

E. How to move on with virology testing

With regard to virology testing, the following questions were discussed:

1. Will the EU directive provide a policy on virology testing and will there be a difference between the EU countries and the non-EU countries?

2. Is it necessary to use better tests (e.g. NAT testing by HIV)?

3. Are more tests needed in case a specific country or region has a higher prevalence for a certain disease?

4. Are test results from non-ET countries reliable?

The discussion was concluded by the decision that a position paper should be established in which the prevalence issue should be included and should provide transparency towards possible new countries joining ET.

F. Procurement, preservation and organ quality

The OPC principally accepted the procurement guidelines presented. It was furthermore decided to add some points of the DSO guidelines to the ET guidelines. Also guidelines regarding transport of organs were accepted as long as these are according to the contracts between the different countries/organizations and ET.

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**Report of the Eurotransplant Financial Committee (FC) meeting**

*Chairman: Prof. Dr. A. van Montfort*

*Secretary: Mr. T. Valkering*

*The meeting of the FC took place on Wednesday, September 8, 2010*

*Members present: 3 + 1 director*

*Members excused: 3*

**A. Announcements**

The FC was informed on developments concerning housing and shared services. On both issues ET could be confronted with extra costs in the future.

In 2009, there were some major changes in the VAT regulations. Therefore, the tax inspector had been asked whether the changes could have any implication on ET’s VAT position.
B. Financial report January – July 2010

The memo “Financial Report January – July 2010” gives some clarification on the financial developments in the past seven months. As all vacancies are filled for the rest of the year it is not expected the result will grow any further. Including the 200 k€ replenishment of reserves, a positive result between 350 and 400 k€ is expected.

C. Budget proposal 2011

It is discussed by the FC that the main differences compared to 2010 are the inclusion of the costs for financial administration of transport and invoicing of registration to the basic budget as they are considered services of the basic mandate. Another change concerns the co-financing of the medical helpdesk by NTS. As NTS has now its own medical helpdesk these services are no longer needed (RFC02.10).

D. Policy on financial reserves

As agreed upon previously, a proposal for a policy on the financial reserves of ET is presented and discussed. The major change lies in a different presentation of the “equity and liability” side of the balance sheet and a redistribution of the former explantation reserve. Structural reserves will be created on “clearinghouse procurement fees” and for “integration of new member states”. Two temporary dedicated reserves are created on housing and reorganization (of the shared services) and a general reserve is created. The proposed amounts can differ when more information is available on future developments. To be able to judge the amounts of reserves financial indicator with standard values are introduced (RFC03.10).

E. Policy on procurement costs

The Financial Committee advises to discuss this policy with the financing authorities and the ET Council. The memo with its two possible procedures is approved. Oosterlee will inform the Board on this subject during the upcoming Board meeting, September 22, 2010.

F. Miscellaneous

Finally it is decided to evaluate the composition of the FC.

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### Report of the EuroTransplant Coordinators workshop on September 23, 2010

During the recent ET annual meeting in Leiden, a workshop for transplant coordinators (TC’s) and ET duty desk officers took place. The workshop was opened by Arie Oosterlee, general director of Eurotransplant. He informed the audience that this workshop was initiated in order to offer TC’s and ET duty desk officers the opportunity to exchange experiences in the day-to-day business regarding organ donation and allocation. It is hoped that this workshop will result in an optimal communication between all parties involved.

The following issues were addressed:

**Organ transport** presented by Caroline Vrijenhoek and Hanneke Hagenaars (TC in the Leiden/Rotterdam region, the Netherlands)

Caroline and Hanneke presented some critical logistic aspects occurring during a donor procedure from a Dutch perspective. Items addressed were lack of uniformity in the area of donor information completeness, duration of allocation procedures, transport boxes in use.

**Communication** addressed by Luc Colenbie (TC in Ghent, Belgium)

Luc demonstrated in a humorous way the importance of communicating with each other in the same – English – language. He had several people in the audience read a donor report in their native language.

**Future of the EuroTransplant Coordinators workshop presented by Tom Karbe (TC in Hamburg, Germany)**

Tom discussed with the audience which topics should be addressed in future workshops. One of the major conclusions of this workshop was that all attendants endorse the interest of continuation of organizing such workshops. The discussions in this first workshop did not result in specific proposals.

The workshop was well attended by 65 participants.

All attendants considered this first EuroTransplant Coordinators workshop as a positive initiative. It could well be that the next workshop will be organized during the upcoming ET winter meeting in Alpbach, Austria (January 26 – 28, 2011).

Please find a questionnaire on the member site of www.eurotransplant.org which provides you the opportunity to fill out your opinion and ideas about this and future EuroTransplant Coordinators workshops.
Chairman: Prof. Dr. Günther Laufer
Secretary: Ellen Houwaart

The meeting is attended by 160 participants.

Opening
The chairman opens the meeting and welcomes all participants.

Election of two Board members A
Liver section
According to the Eurotransplant Articles of Association, the current Board member A in the liver section, Prof. Xavier Rogiers from Ghent (Belgium) has to be (re)-elected. Since no other candidates applied for this position and Prof. Rogiers had declared to be available for another term, he is re-elected by the Assembly.

Pancreas section
According to the Eurotransplant Articles of Association, the current Board member A in the pancreas section, Prof. Wolfgang Schareck from Rostock (Germany) has to be (re)-elected. Since no other candidates applied for this position and Prof. Schareck had declared to be available for another term, he is re-elected by the Assembly.

Announcement of the winner of the Henk Schippers Young Investigators award
The Assembly chairman invites Eurotransplant’s president, Prof. Bruno Meiser to announce the 2010 winner. Prof. Meiser together with Mrs. Hanneke Siebers, the widow of the late secretary/treasurer, Henk Schippers, present Dr. Robin Vos from the University Hospital Leuven, Belgium

with the 2010 Henk Schippers Young Investigators award. Dr. Vos is congratulated with this prize and is invited to present his data during the Eurotransplant winter meeting in Alpbach (Austria), January 2011.

The following presentations were also given during the Assembly. Since they will be published in this issue of the ET Newsletter, there is no need to further elaborate on these presentations in this report:

- Presidential address by Prof. Bruno Meiser
- Directors report by:
  - Arie Oosterlee, general director
  - Axel Rahmel, medical director

Prof. Laufer closes the meeting at 17:00 hrs by thanking all attendants for their participation in this informative meeting.
Distinguished guests of the Eurotransplant community,

The objective of this report is to be accountable to you for the activities and initiatives that were undertaken since the last annual meeting in Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands and Slovenia.

Many milestones have been reached in the past period. Many have been described in our annual report that has been made available to you all. There are a few topics that I would like to mention.

For ET, 2009 can be seen as a year in which many steps were taken to further professionalize our services for professionals and also for national authorities.

The following processes and activities are reported according to the services mentioned in the Basic Mandate we have been given by our contract partners: the National Authorities.

- **Allocation services**

  The allocation process was reinforced by succeeding in finding suitable candidates for the staff of our duty desk.

  An electronic donor log application was developed and implemented, greatly supporting the duty desk officers in their task of managing and documenting information during allocation procedures.

- **Development of allocation process**

  The by the EU funded project EFRETOS is halfway its completion. (European FFramework for the EvaluaTion of Organ transplantS) The goal of the project is to develop common definitions and methods as well as the technical and operational specifications for a so-called registry of registries for the evaluation of organ transplantation in the EU member states. This project is conducted by a consortium of European organizations from inside as well as outside the Eurotransplant area.

  The European EFRETOS project and the ET registry policy were harmonized wherever appropriate.

  Reinforcement of the biostatistical capacity was started by initiating the hiring of an additional biostatistician.

- **External networking**

  In the field of external networking several important developments took place in the ET Council. This Council was established giving national authorities a formal platform to discuss issues and concerns on a supranational level with the Board of ET.

Since last meeting this Council met once. A summary of the conclusion of previous meetings was printed in a booklet “Organ Donation: Towards a Mutual Understanding”. Available to those who are interested at secretariat@eurotransplant.org.

The council agreed that ET should coordinate a harmonized implementation of the recently adopted EU Directive on standards of quality and safety for human organs intended for transplantation. As a first step ET will develop and propose definitions in the context of organ vigilance for serious adverse events.

The Council also asked ET for a policy on expansion to new member states, considering benefits and assessing potential risks for patients on our waiting list. In follow-up on this request ET performed a risk benefit analysis and developed a systematic way to expand carefully in the event such opportunities arise.

### Accession procedure

1. Interested state (currently Estonia, Serbia and Hungary)
2. Compliance to prerequisites
3. Risk assessments:
   - HLA diagnostics
   - Demographics
   - Logistics
   - Legislation
   - Sovereignty
   - Safety for professionals
   - Costs
4. Negotiation of 1st step: preliminary cooperation
5. Evaluation
6. Accession

**Support**

ET succeeded in attracting an experienced communication officer. No doubt, Sandre Douma will help us improve and professionalize our communication with you and the outside world.
In the area of planning & control several steps regarding organization and responsibilities were taken.

A function was set up for project and program management as well as test coordination. In its short existence a significant improvement in management information was achieved which strongly enhances prioritization, planning and decision making by the directors.

Financially ET is in better shape than a couple of years ago. We ended the year positively and that enabled to partly replenish our almost depleted reserves.

An analysis of the reserves resulted in a (re) definition of our reserves and reserve policy.

**Future plans**

As before, the ET Policy Plan 2009–2013 will provide guidance in 2011 for developing plans and activities. The consolidation strategy will be sustained, whereas we will remain open for discussion with countries that want to explore possibilities for cooperating with ET.

Regarding the internal organization three related developments will specifically demand attention in the coming period:

ET, NTS and NBF-BIS currently share vital infrastructure i.e. computer hardware and software, telecommunication equipment etc.

Due to legislative developments in the Netherlands, the economies of scale and scope that ET experienced by sharing personnel with two other organizations are currently under discussion.

For this reason it has been decided that a separation on the vital infrastructure has to be realized in a systematic and controlled way in the near future.

Ladies and gentleman, your organization is in good shape with many interesting developments being in progress.

The future looks bright ...........

.... But only as long as you are able to keep finding enough young talent to fill the duties and do the research in the future.

There is a fierce competition for talent going on for talented young professionals such as doctors, nurses, lab technicians. We do not want to lose them all to pursue a career outside transplant medicine. Inspire these young people during their training so they return later to work in your clinic.

I speak from experience, when I worked as a transplant coordinator; I was very much inspired and therefore returned many years later.

**THANK YOU!**
Medical Directors Report
By Dr. Axel Rahmel

Eurotransplant
Medical Directors Report
Axel Rahmel
Leiden, September 23, 2010

Topics
- Waiting list
- Donation
- Transplantation

Kidney Waiting List and Transplants
Eurotransplant 1959 - 2009

Liver Waiting List and Transplants
Eurotransplant 1995 - 2009

Lung Waiting List and Transplants
Eurotransplant 1995 - 2009

Heart-Lung Waiting List and Transplants
Eurotransplant 1995 - 2009

Pancreas Waiting List and Transplants
Eurotransplant 1995 - 2009

*including kidney and islet transplants
Liver Transplantation
January 1 – August 31, 2010

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Deceased Donor Split Liver Donations
Eurotransplant 2002 – 2010
by transplant country

Deceased Donor Split Liver Transplants
Eurotransplant 1993 – 2010

Heart beating / Non-heart beating donor kidneys, transplanted in the Netherlands
1995 – 2010

Special Thanks to:
ET Medical Staff,
Dave Green, Erwin de Vries, Agita Strelniece
Dear colleagues and friends,

I have the privilege to report about the recent developments concerning our organization. The directors will certainly give you in their report further information about more internal issues like shared services, housing or the development of a new Eurotransplant homepage. Therefore, I would like to concentrate on rather political issues.

An important event in that sense was the meeting with the new European Commissioner for Health and Consumer Policy, John Dalli. On July 24 this year, he came to Munich to participate in a “round table discussion” with the Eurotransplant International Board. The commissioner was accompanied by a member of his cabinet, Mrs. Paula Duarte Gaspar. From the Eurotransplant side, Board members representing the Eurotransplant member states and the Eurotransplant directors participated. In addition, I had invited Prof. Robert Langer from Semmelweis University and the Bavarian Minister for Justice Beate Merk - since one of the subjects was the implementation of the new Directive on “standards of quality and safety for human organs intended for transplantation” into national legislation.

After introducing the commissioner to the structure and goals of Eurotransplant, he gave a speech which is actually summarized in the most recent Eurotransplant Newsletter (218). He emphasized that Eurotransplant has been a model and inspiration for important parts of the new Directive. He praised Eurotransplant being a pioneer in setting up a transparent international organ exchange system and elaborated on our leading role in Europe for matching organs between donors and potential recipients. We then moved on to discuss the contents of the Directive, benefits expected from the implementation, potential risks associated with it as well as the pro and cons of the exchange of organs and the migration of patients within the EU and the Eurotransplant area.

During our discussion, the fundamental importance of the risk-benefit ratio as the base for this Directive was underscored – meaning that the overall benefits of organ transplantation are very high - and considering the tight time frame for organ harvesting and transplantation, more risks can and have to be accepted than with blood or most tissues and cell based treatments. The Directive sets out the information required for this assessment and we emphasized that it is very important that the national governments do not start to over regulate organ donation and transplantation – and even worse, each country might carry this out in a different fashion.

As an international organ exchange organization, we have to make sure that the information legally required is similar in all our member states. We asked the commissioner to support us in our efforts to harmonize the respective data sets. Just imagine what will happen if State A requires much more detailed donor information than State B. This could lead to the situation that the organ from a donor in State B cannot be accepted by a center in State A because a part of the information required in State A is missing. We suggested that our Advisory Committees will give recommendations for a harmonization of these standards and the commissioner underlined that the input from Eurotransplant will be most appreciated.

Soon after this meeting with the Commissioner, Eurotransplant participated in the first meeting of the future national competent authorities for organ donation and transplantation in Brussels. The director and I took part in order to continue our efforts for a harmonization of the respective definitions, characterizations and mandatory donor data.

In the meantime, several member states indicated their intention to either make Eurotransplant a part of their national competent authority for organ donation and transplantation or to delegate a part of the tasks assigned to the competent authority to Eurotransplant.

One of the important roles Eurotransplant could have in the future would be the building up of the registry of registries. I suppose that we will hear from our general director that the EFRETOS-project is progressing well. After Eurotransplant as the project leader will submit the report to the European commission, there will be a call for tender for this registry as the project leader will submit the report to the European commission, there will be a call for tender for this registry of registries and I suppose that we will have a good chance to be at least one of the major candidates for hosting this registry.

We had another meeting of the Eurotransplant Council in May of this year. The main issue besides the new EU-Directive were the balancing rules in international organ exchange as well as patient migration. It was discussed that the aspect of cross-border exchange is not only a medical but rather a socio-political issue. Patients migrate for different reasons: in some cases a medical center across the boarder is closer than a national center. Many times, however, the patients migrate for shorter waiting times based on higher donor rates in another country. Furthermore there might be differences in medical indications and screening criteria for transplantation between member states.

On the other side, free mobility and free access to health care for all citizens of the European Union is legally guaranteed.

The Council members concluded that this problem certainly cannot easily be solved since borders cannot be closed for patients, self sufficiency of the member states will not be
realized in the short or medium term and harmonization of screening criteria is difficult to achieve considering the independence of medical decisions.

Therefore, it might be necessary to create some kind of disincentive for patients moving from one country to another. One option could be the multiplication of waiting time with a factor smaller than one in order to adjust the chance to receive a transplant in a neighbouring country to the chance the patients have in their own country. This has to be discussed very thoroughly, always keeping in mind the obligation to help all patients independent from the nationality but also not endangering the solidarity within a country with respect to the preference to donate organs for fellow countrymen in the first place.

I reported during my last presidential address about our efforts to support states interested in becoming a candidate for membership in Eurotransplant.

Over the last year, 3 states particularly continued with these efforts - one being Estonia. During our meetings and discussions with the Minister of Health, it became clear that several issues in legislation as well as in organization of transplantation need further clarifications and changes. In the mean time, the Ministry assigned working groups to work out the necessary programs as well as to prepare the legislative changes. The Minister recently expressed his expectation that the adjustment will be carried out in a fast fashion so that Estonia would become a trusted partner for an international organ transplantation organization – which should be Eurotransplant - and I would like to welcome a delegation from the Tartu University Hospital headed by Peter Demetriev.

The second country which has started considerable efforts to improve the standards and to meet the prerequisites for becoming a member of Eurotransplant is Serbia. One issue is the accreditation of the tissue typing centers in Belgrade and Novi Sad which is being worked on. Furthermore, since the donation rate in Serbia used to be very low, the Serbian minister of health promoted actions to increase donation and started to restructure the organization in the Ministry and in the hospitals. He has sent me these data a couple of days ago showing a significant improvement in donation rate and indicating that Serbia is on a very good way, but still needs some time.

Another very promising development happened with respect to Hungary. You might remember that we had already negotiated a cooperation agreement in 2007. Due to several changes in the government as well as objections from the medical establishment, this project was not further pursued. However, mainly due to the personal initiative of Robert Langer, the new head of the department of transplantation and surgery at Semmelweis University, the project became a new momentum. We had a meeting with Prof. Langer in November last year, discussing the situation and the options for further proceedings - and in June of this year, he organized a “round table discussion” with key figures from the Hungarian transplantation society, the national blood bank institute, the ministry of health and several university medical centers. The directors and I finally met the acting Minister of Health in mid September. We discussed the pros and cons of a preliminary cooperation agreement extensively and I am convinced that Hungary is on a good way to become a preliminary member of Eurotransplant in the near future.

Nevertheless, it is not our intention to enlarge our foundation by all means. Therefore, we developed a policy on expansion, defining the prerequisites for joining Eurotransplant. There are many different aspects we have to consider. There are the formal and legal questions including legislation allowing organ exchange, logistical prerequisites - for example a 24 / 7 duty desk with staff capable to communicate in English - as well as medical prerequisites like the standardization of brain death determination or accreditation of HLA laboratories.

The expansion of Eurotransplant is certainly important for strengthening the organization in order to be well prepared for the future. Benefits are for example increased organ availability and increased quality control on donor organs coming into Eurotransplant since member states have to adhere to our standards. Potential risks are for example logistical risks in transporting procurement teams or organs, increasing distances between procurement centers and recipient centers, potential imbalances in organ exchange if a country has a very low donation rate, etc. Therefore, each application for membership has to be evaluated individually, considering all aspects very carefully before we go any further.

Thank you very much for your attention.
Travel regulations to Croatia broadened – ID card or driver’s license are now accepted!

In contrast to information in the previous issue of the ET Newsletter, travel regulations to Croatia have been broadened: the regulation that traveling to Croatia is only possible with a valid passport has been canceled.

Thanks to negotiations between our Croatian Board member and the Croatian airport-, custom-, cargo- and police authorities, from now on procurement teams from EU countries are allowed to enter Croatia with a valid ID card or other identification document (with photo!).

It is hoped that this more flexible regulation regarding the entrance to Croatia will ease organ procurement procedures!

Implementation of recommendation regarding intestine and pancreas allocation sequence

During the Board meeting on January 27, 2010 in Alpbach, there has been an agreement on the following recommendation. The approval of this recommendation was already communicated in ET Newsletter 217, March 2010. At that time authorization by the national authorities of Belgium, Germany and the Netherlands was still awaited. In the meantime these authorizations have been received.

RET01.09
The allocation sequence shall be changed in such a way that intestine allocation has priority over pancreas and kidney allocation so that the resulting sequence of allocating donor organs shall be:

Thoracic organs -> Liver -> Intestine -> Pancreas -> Kidney.

In case the intestine and pancreas of a donor are allocated to two different recipients, it is strongly recommended that experts for pancreas and intestine procurement are both present at the donor procedure, aiming at retrieving both the intestine and the pancreas for transplantation. If in case of a combined intestine and pancreas donor either the pancreas or the intestine cannot be procured or transplanted due to procurement related reasons, detailed information has to be provided to the Eurotransplant office. This case will then be forwarded to the OPC, the ELIAC and EPAC and discussed.

The change in the allocation sequence will be evaluated one year after the implementation.

Eurotransplant will implement this recommendation as per December 8, 2010. From this date on intestine allocation will have priority over pancreas allocation.

The Eurotransplant Senior HLA-DR allocation Program (ESDP) has started

On October 6, 2010 a new senior allocation program, ESDP, started in Austria, Belgium and Germany. In the Netherlands this program already started in November 2009. Prof. Hans de Fijter (principal investigator) from the Leiden University Medical Center in the Netherlands together with Eurotransplant decided to allocate kidneys from donors ≥65 years according to the ESDP protocol. For better understanding of the changed allocation, a short summary of the allocation procedure and inclusion of patients into the study is presented below:

- **Allocation**
  In case of a heart beating kidney donor ≥65 yrs with the HLA-typing available within 4 hrs after procurement, one kidney will be allocated according to the current ESP rules, while the other kidney will only be offered to patients from the ESP match list, who have a complete HLA-DR match. According to this allocation scheme the HLA-DR matched patients will in general have a lower rank position on the match list than the not-matched patients. Therefore the right to decide to choose the left or right kidney for the recipient cannot be linked to the rank position on the match list, but will be randomized between the two groups.

- **Data collection**
  If both patients are agreeing to data delivery for the ESDP study, the patients will be formally included into the follow-up part of the study including the reimbursement for data collection. Therefore it is necessary to indicate at the time of registration of the transplantation, whether the patient is willing to participate in the data collection. The official contact persons of transplant centers will receive an automatic notification via e-mail with the information, whether the patient is included in the follow-up part of the study or not.

All details of the study protocol can in addition be accessed and downloaded from our website (please go to the ET-member site, on the top of the left hand column you will find a link to “ESDP”).

In order to allow a smooth start of the new allocation procedure, it is emphasized that the most important aspect of the changed allocation, is reporting donor HLA prior to making an ESDP match. Without the HLA report allocation cannot start.

Therefore all donor centers are requested to give special attention to donors of ≥65 years from now on and to report their HLA as soon as possible. With this you are invaluable in contributing to the success of the changed allocation.
Implementation of recommendations announced in the previous ET Newsletter (218)

The following recommendations that were approved by the Board during previous Board meetings, will be implemented as per December 8, 2010

**RKAC03.08**

Recipients suffering from end stage renal disease after having donated one of their own kidneys, are eligible for pre-emptive listing on the kidney waiting list. The recipient will be granted an allocation bonus of 500 points upon listing.

**RKAC01.09**

If one or more consecutive kidney transplants fail requiring maintenance dialysis within 3 months after transplantation, and the recipient is re-entered on the waiting list, waiting time will be returned starting from the dialysis time before the first failed transplant.

**RKAC02.09**

Children either on dialysis or registered on the Eurotransplant waiting list before the age of 16, should be granted a pediatric status until their first successful graft, irrespective of their age at the time of an offer. In case of a pre-emptive registration on the kidney waiting list, the pediatric status will end on the 17th birthday, if dialysis is not initiated before this date. Recipients on dialysis or registered on the waiting list after their 16th birthday will be granted the pediatric status provided that they are proven to be in maturation. This proof has to be delivered by the transplant center by a report of a competent radiologist or pediatric endocrinologist on an X-ray of the left hand that has to be sent to and judged on by two independent auditors appointed by Eurotransplant.

The pediatric status will be withdrawn when dialysis does not start within one year after registration, but will be restored when the recipient fulfills above criteria for maturation at time of institution of dialysis.

The effect of these changes should be evaluated after 2 years.

**RKAC03.09**

In case of a donor <16 years of age recipients having the pediatric status are listed directly after 000 HLA mismatched recipients, provided that the recipient specific donor profile on maximum donor age and accepted HLA mismatches is entered into ENIS. The ranking order among these recipients should be according to the ETKAS overall point score system.

**RKAC04.09**

The current, age dependent, pediatric bonus should be replaced by a uniform bonus of 100 points for all recipients having the pediatric status.

**RKAC01.10**

In addition to the option of performing a combined liver-kidney transplant the option of a kidney-after-liver transplant should be made possible in selected cases. If a recipient is listed for a liver and kidney transplant, the center can decide to perform a simultaneous liver-kidney-transplant or a kidney-after-liver transplant. In the latter case the recipient gets 500 extra points in the kidney allocation system (ETKAS) during the period of 90 to 360 days after the liver-only transplant, under the condition that the creatinine clearance is <15ml/min within this period.

**Rlac05.09**

HU status for liver transplant recipients has to be re-evaluated every 14 days. At the time of re-evaluation the number, and if requested, also the details of a turned down liver organ offer in the preceding 14 days have to be reported to the auditors. Patients in HU status who become (temporarily) not transplantable have to be reported as NT and will at that moment lose the HU status and the so far accumulated HU days.

**RPAC01.10** (only applicable for Germany)

In Germany pancreata that cannot be allocated via standard allocation and all pancreata from donors >50 years of age and with a BMI >30 are allocated via rescue allocation. If a pancreas allocated via rescue allocation turns out to be not suitable for vascularized organ transplantation, it can be used for islet transplantation. If the pancreas is already in a center that also performs islet transplantation, it can be directly forwarded to this islet program. If this center has no islet program, the pancreas should be forwarded to the nearest islet program. The islet program selects from its waiting list the patient best suited for transplantation after islet isolation.

ET maintains a service of documenting the waiting list for islet transplant recipients. The islet transplant programs will be provided with their waiting list to facilitate the selection of the best suited islet recipient. For sake of proper documentation, the islet transplant programs are obliged to register every islet transplantation in the ET computer program ENIS.

**RPAC01.10** will be re-evaluated one year after implementation.

**RPAC02.10**

The SU status for pancreas islet transplantation limited to a national level can be re-instituted upon request of an ET member country. The pancreas islet SU criteria have to be defined by the respective national organ specific Advisory Committee.