Alliance-O
Work Package 4
INCREASE SAFETY AND QUALITY IN ORGAN TRANSPLANTATION

Deliverable 4.1
STATE OF THE ART OF SAFETY PROCESSES, EXCHANGE OF BEST PRACTICES

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Introduction

No transplantation process is completely safe. It may entail risks for the recipient and the possible living donor [*references A*]. In each case the potential clinical and psycho-social benefits of the transplant procedure should outweigh the risks [*references B*].

Moreover, the shortage of organs is probably the most important issue in transplantation in most countries [*references C*]. Success of transplantation therefore depends on several factors, related in part to recipient health conditions, in part to donor characteristics [*references D*]. The process of evaluation of organs suitability can be largely influenced by the balance between donor-related risks of disease transmission and expected clinical benefits for the recipients [*references E*]. Moreover, the time constraints due to ischemia of organs may preclude performing certain screening procedures [*references F*]. A set of specific tests are usually performed in order to avoid the transmission of infectious diseases or tumours from donor to recipient.

The organizational differences in partner countries should be analysed for their importance in reducing risks of disease transmission in organs transplantation [*references G*].

Materials and Methods

In this project, we have made a study to collect and compare the tests performed in different European countries, mainly focused on the transmission of transmittable disease between deceased donor and recipient, for different reasons:

- living and deceased donors have to be differently evaluated, since the first need pre-donation counselling, informed consent, additional legal requirements and short and long-term psychological attitudes that should also be taken into account;
- living donation is not encouraged in all countries;
- a better utilization of available organs from deceased donor is a prompt tool for expanding the existing donor pool;
- bad transplant outcomes for disease transmission may impact very negatively on public opinion, thus reducing further positive attitude to cadaveric organ donation;
- a definition of harmonized European measures for such risk evaluation is needed and following common follow-up data that are presently not collected.

In order to make the inventory and possible revision of existing national guidelines on safety rules, we conceived a questionnaire that had the purpose of collecting information on the process of evaluation of the cadaveric donor suitability running in the partners countries and on the tools utilised to collect the information related to donors and recipients in transplants at risk for infectious or neoplastic disease transmission. The evaluation of organ suitability has the goal of assuring that any organ retrieved for a transplant has a high level of safety and it does not put the recipient at unacceptable risks.

The questionnaire was circulated among partners in December 2004, results were presented and discussed during a March Consensus meeting, further analyses were later performed with a validation of results. Data from the questionnaire will also be used to lay down a common position on this subject (deliverable 4.2 – under preparation - to be submitted end September 2005).

The questionnaire was divided into three main sections:

1. Structure of the organization;
2. Anamnesis and tests performed;
3. Informatics aspects

For a full overview of the questionnaire structure, see Annex 1.

The first main aspect we wanted to detect is how the national structure(s) of the organization(s) is (are) organized, if there is only one main national body, several regional bodies or only a supranational body. Functions of the organizations have been analyzed and we asked how the different tasks are managed, if at a supra-national, national or regional level. We have prepared questions to test who is in charge of coordinating organ donation and allocating organs, regulating transplantation procedures and organ distribution, carrying out audits, analyses and statistics, managing the educational part (organization of training courses, lectures, etc.) and the ethical issue related to the transplantation. Moreover, one of these questions was about the level (supranational, national or local level) at which the protocols are elaborated.

The following set of questions has the aim to know if the national organization is competent for organs, tissues and haematopoietic progenitors. In this part the goal has been to understand who is in charge of donation and transplantation activities, to analyze donor selection criteria, how the criteria for donor selection are regulated and which contraindication have been treated by regulations.

The second part of the questionnaire is focused on the clinical aspects related to the safety of the organ donor. We asked partners what kind of information they usually collect for the evaluation of the donor suitability and which additional tests they perform before accepting any organ donor. This section was prepared in accordance with the "Italian General Criteria for Evaluation of Donors Suitability" issued on November 26th 2003 and in cooperation with the consortium partners. Such information is essential for having a picture of the European area and most of all for the identification of common risk categories.

A list of collected information on medical and behavioural history of the potential deceased donor was drawn up (Table 1).

Table 1: kind of information collected from medical history for donor evaluation
Anamnestic information available
Risk factors for HIV/hepatitis
Previous Infectious Diseases
Illicit substance abuse
Neoplastic Diseases
Familiar history of malignancies
Recent PSA value available (for patients with >50 years)
Surgical interventions
Menstrual dysfunction
Pregnancy status
History of recent miscarriages
Cardiovascular diseases
Pneumopathies
Liver diseases
Renal disorders
Diabetes
Autoimmune disorders
Hypertension
History of chronic drug use
Dislipidemia
Alcohol consumption
Smoking status
Diseases of unknown etiology

Results

A. Structure of the organization

Regarding the structures of organizations, in three countries (France, Hungary and Spain) there is only a national body coordinating all the transplant activities whereas in Portugal and Italy there is a national body but also several regional bodies. In Germany DSO is the national organization. It is subdivided into seven organizational/administrative regions (which are all part of the DSO) in order to meet local needs of hospitals and transplant centers. The only nation with a supra-national body is UKT in charge of England, Scotland, Wales and Northern Ireland.

Organizational functions differ in the participating countries. In three countries (Germany, Italy and Spain) there is a national body in charge of coordination, whereas in the UK there is one supranational structure and several national and regional structures. In Portugal and Hungary, the network is coordinated both at a national and a regional level whereas in France it is only coordinated at national and inter-regional levels by the ABM.

The DSO is not responsible for the allocation of the procured organs. In charge of the Allocation is Eurotransplant International Foundation, a private foundation responsible for the Allocation in its six member States: Germany, The Benelux, Austria and Slovenia. The recipients are chosen from a joint (inter)national waiting list. HT is not responsible for allocation, the four kidney transplant centers follow common rules. In all other countries there are always some regional structures in charge of it. In Italy, Spain and France there is also a national body in charge of it and in the UK there is a supranational body and national ones.

Portugal and Spain replied a national body is in charge of regulating transplantation procedures, Italy replied there is a national body and regional structures in charge of it whereas UKT replied it is managed at a supranational, national and regional level and ABM replied it is managed at a national and regional level. The DSO respectively its coordinators are responsible for the whole process of organ procurement up to the point of time when the organs are preserved packed and shipped forward to the transplant centre. In Hungary the Transplantation Society, Ministry of Health and the Waiting List Committees and HT are in charge of regulating transplantation procedures.

For organ distribution the replies were the same as organ allocation.

In five countries, Germany, France, Portugal, Hungary and Spain, the national organization is in charge of carrying out audits, data analyses and statistics. Italy replied they are carried out by national and regional bodies whereas in the UK they are carried out by supranational and national structures.

In every country there is a structure at national level who is always involved in the development of protocols. In Italy also interregional and regional Organizations are in charge of it and in the UK all the three levels (supranational, national and local) are taken into account.

In four countries, Germany, Portugal, France and Spain, the national organization promotes, regulates and manages educational programs, such as training courses, lectures, masters, public events, etc. Two other countries, Hungary and Italy, these are regulated both at a national and regional level and in the UK there is also a supranational level.

The last question of this section regarding the organizational part who is in charge of the ethical issue related to the transplantation. In Hungary and France, national and local Ethical Committees are functioning, the other national organizations are in charge of it. In Italy there are also regional bodies involved in it, and supranational structures in the UK. DSO is also directly involved in donor detection and organ procurement.

All the national organizations are competent for organs. The DSO is responsible for solid organs only. Responsible for tissues – in particular cornea- is the DSO-G that is an affiliated foundation of the DSO, however independent. All the other countries are competent for tissues (UKT specified corneas). Regarding haematopoietic progenitors, ABM, OPT, CNT, ONT are competent, whereas DSO, UKT, HT are not in charge for it.

With regards to donation activities, all national bodies are in charge of quality and safety of organs as well as the development of regulation related to donation and the transplantation activities, apart from UKT. DSO and ABM specified they are only in charge of proposing regulations.

Accepted cold ischemia times differ from country to country. In HT and ONT there are no strictliy defined cold ischemia times, the transplant surgeon holds the responsibility to accept or refuse an organ. Times for liver are more homogeneous than others. ABM, UKT and CNT declared that they accept up to 12 or 16 hours of cold ischemia time (that is the Gold standard for UK will accept above 16 hours on case by case assessment), while

DSO up to 16 and OPT up to 20. Kidney accepted times vary from a minimum of 24-36 (same with kidneys) hours of UKT to a maximum of 48 hours of ABM. In between we find a limit of 26 hours given by DSO, 36 hours by OPT and CNT accepts 24 to 36 hours. Heart acceptable times vary from 4 hours of ABM and UKT to 8 hours of DSO. OPT accepts up to 6 hours and CNT up to 7. Lung ischemia times diverge country to country. ABM accepts 6 hours at most while Italy 7 and UKT 8. DSO and OPT respectively accept 10 to 12 hours and 12 hours. In three countries, UK, Portugal and Italy cold ischemia time is regulated by guidelines. In Germany there are no guidelines on it. In the other two countries, Hungary and Spain cold ischemia time is regulated both by law and guidelines.

In all countries are the Ministries of Health in charge of issuing laws/guidelines. In Germany the necessary tests for recipient safety that have to be done are laid down in an appendix to the contract of the DSO with the insurance companies, the German Hospital Foundation and the German Medical Association that was signed in 2000. The guide to quality and safety of the COE is paramount. In France the decree is dated 9th October 1997, in the UK the guidelines were issued in 2000 whereas in Portugal they were issued in October 1995. In Hungary the law was issued in 1997 and further decrees followed. In Italy the guidelines were issued in 2003 whereas in Spain the laws are dated 27th October 1979 and 30th December 1999.

In Portugal, France and Hungary only infections are treated by regulation, whereas in UK, Italy and Spain both infections and neoplasia are treated by regulations. In France, neoplasia is treated by guidelines in the donor selection file.

B. Medical history and tests performed

All countries collect a high level of information related to the donor medical history. Only CNT and ONT collect all information detailed in the questionnaire, while all other organizations do not collect more than six categories of information, as shown in Table 2.

Table 2: categories of information not routinely collected in different organizations

Familiar history of malignancies	ABM, HT
Recent PSA value	DSO, ABM, UKT, HT
Menstrual dysfunction	DSO, ABM, OPT, HT, ONT
History of recent miscarriages	DSO, ABM, HT
Autoimmune disorders	HT
Dislipidemia	DSO, ABM, HT
Exanthematic disease (pediatric donors)	DSO, ABM, UKT

Results show that all countries gather most of the information which is important to evaluate the donor and to have a clear picture of his recent and past conditions.

As concerns laboratory serological tests, in addition to the minimum tests foreseen by the "Guide to safety and quality assurance for organs, tissues and cells – Second edition" published by the Council of Europe, we decided to collect information also on the tests that may be required in specific situations (Table 3).

Table 3: serological tests carried out in organ donors

ROUTINARY SITUATIONS
Anti HIV
Anti HCV
HBsAg
Anti HBsAg
Anti HBcAg
Syphilis (TPHA/VDRL)
Anti CMV (IgG and IgM)
Toxoplasma (Antibody)
SPECIFIC SITUATIONS
HDV (if patients HBsAg positive)
EBV (anti-VCA and anti-EBNA antibody)
HSV-2 (IgG)
VZV (IgG)
HSV-1 (IgG)
HTLV-1/2

Some of the above mentioned serological tests are not required in a few countries. The situation is slightly different comparing to the previous one and results are much more heterogeneous. This is probably due to the fact that to date Italy and Spain are the only two countries who adopted guidelines for the evaluation of organ suitability in case of donors affected by infective and/or neoplastic diseases. France is going to issue a very detailed decree on this matter, under which a 5-year program will be started for controlled use of HCV and HBV positive donors (except AgHBs positive donors). Results of the questionnaire show that the situation is heterogenous. Tests are performed by all countries, while some others are not required in many countries. Many organizations do not require tests for the detection of Herpes virus and Hepatitis Delta while all countries have to carry out tests on HIV, HTLV, Hepatitis B, C and Syphilis. In Table 4 results are shown country by country for each type of test not performed.

Table 4: type of test not performed

Anti HBsAg	HT
AntiHBcAg	HT
HDV (if patients HBsAg positive)	DSO, ABM, OPT, HT
HSV-1(IgG)	DSO, ABM, OPT, HT, ONT
HSV-2(IgG)	DSO, ABM, OPT, HT, ONT
EBV (anti VCA and anti EBNA antibody)	HT, ONT
VZV (IgG)	ABM, UKT, OPT, HT, ONT
Toxoplasma (antibody)	OPT, HT

On the other side all countries require the following fundamental tests:

- Anti HIV,
- Anti HCV,
- HBsAg,
- Syphilis (TPHA/VDRL),
- Anti CMV (IgG and IgM).

Instrumental tests such as ECG, chest radiography and abdominal and pelvic ultrasonographic examination are performed in all countries except for Hungary, where

only chest radiography and ECG are required. In many cases echocardiography is not performed and this is true for DSO, UKT (not routinely) and HT. These countries do not require the execution of the mentioned test although they do all the others. These results may belong to the procedures applied in each country for the brain death diagnosis, which might be slightly different country to country.

Tumour markers are not required in any country. However DSO, OPT, HT, CNT and ONT test tumour markers whenever the characteristics of the donor require this further investigation. When PSA test is performed and the result is positive, only CNT and ONT proceeds with the transrectal ultrasonography and if this one is also positive they make a biopsy.

Emerging diseases are becoming a topic for all organizations because more and more cases of donors affected by an emerging disease have been recorded. However, still only ONT tests a few of them, namely HTLV and malaria, while HTLV is also routinely performed in France.

Some questions were added about the possible existence of second opinion groups. The aim of such initiatives is making expertise available on main organizational and decision-making processes in transplant organ evaluation, thus minimizing risk of disease transmission through shared procedures and good clinical practice. The setting up of such group is useful for giving additional support to the health care professional of transplant centre who is still the main actor in the process and the only entitled to final choices. The survey showed that DSO, CNT and ONT set up a group of experts to turn to for doubtful cases. In Italy the group is composed of a histopathologist, a coroner and an expert in infectious diseases, while in Spain they foresaw only two experts: the histopathologist and the expert in infectious diseases. Each of the seven DSO sub-regions is headed by an administrative medical director who is an expert in organ donation/transplantation. In doubtful cases he/she is contacted for a second opinion. Experts of the three countries receive a reimbursement for their assignment.

C. Informatics aspects

Since the information to be collected during the assessment of donor suitability should be promptly shared by the network of transplant centres and experts, an *ad-hoc* section was added with questions on how such data are presently transmitted and/or stored. This

section has been developed on the basis of some ongoing experiences that exploit new technologies for supporting decision-making in safety issues. Results show that DSO and CNT are the only two countries who implemented a tool for expressing second opinions. DSO utilises fax and telephone to express the second opinion and they record data in a dedicated information system. DSO utilizes these tools for cases donors at risk of infectious disease transmission and of tumour transmission. CNT utilizes a dedicated information system, telephone, fax and video-conference to express the second opinion and the dedicated information system to allows to record the data on the cases treated by the group of experts. So far this tool is utilised only for cases of donors at risk of infectious disease transmission and not for those at risk of tumour transmission.

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ANNEXES

ANNEX 1
RESULTS OF THE QUESTIONNAIRE (see text)

STRUCTURE OF ORGANIZATION	DSO	ABM	UKT	OPT	HUNGARO TRANSPLANT	CNT	ONT
Supranat.body			Public				
National body	Public	Public		Public	Public	Public	Public
Regional bodies	Public			Public: regional coordination offices		Public	
Functions							
Co-ordination of organ donation	National	Nat/region.	supr/nat/reg	Nat/region.	Nat/region.	National	National
Organ allocation	In charge of the Allocation is Eurotransplant	Nat/region.	supr/nat/reg	Nat/region.		Nat/region.	Nat/region.: Kidney:nat exchange rules for hyperimmunized patients
Oversight/regulation of transplantation procedures	National	Nat/region.	supr/nat/reg	National		Nat/region.	National
Organ distribution	In charge of the distribution is Eurotransplant in cooperation with the DSO coordinator	Nat/region.	supr/nat/reg	Nat/region.		Nat/region.	Nat/region.: Kidney:nat exchange rules for hyperimmunized patients
Statistics/analysis/audit of organ donation and transplantation	National	National	supr/nat/reg	National	National	Nat/region.	National
Elaboration of protocols, recommendations, consensus documents, etc	National	National	supr/nat/reg	National	National	Nat/region.	National
Training, courses, lectures, etc	National	Nat/region.	supr/nat/reg	National	Nat/region.	Nat/region.	National
Ethics of Organ Transplantation	National	National	supr/nat/reg	National		Nat/region.	National

Functions	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
Other	Donor detection, evaluation, maintenance, support in brain death diagnosis, support in HLA typing, support in quality and safety procedure, organisation of procurement, transport, support in quality control and statistics	Evaluation of results, Good Practices, Organisational and funding strategies					
Scope of activities							
Organs	Yes	Yes	Yes	Yes: Also private-Portuguese Red Cross	Yes	Yes	Yes
Tissues	No (DSO-G: affiliated foundation for tissues)	Yes	Yes corneas)	Yes	No	Yes	Yes
Haematopoietic Progenitors	No	Yes	No	Yes	No	Yes: also cell therapy	Yes: Also cell therapies
Is your organization responsible for these organ donation activ.?							
Quality and safety of organs	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Development of Regulations	German Medical Association is responsible for the issuing of respective guidelines. DSO representatives participate on the committee (Special committee for organ transplantation at the German Medical Association) that is in charge of the guidelines.	Yes	No	Yes	Yes	Yes	Yes

Is your organization responsible for the following organ transplantation activities?	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
Quality and safety of organs	Yes	Yes	Yes	Yes	No	Yes	Yes
Development of Regulations	German Medical Association is responsible for the issuing of respective guidelines. DSO representatives participate on the committee (Special committee for organ transplantation at the German Medical Association) that is in charge of the guidelines.	Yes (proposition)	Yes	Yes	No	Yes	Yes
Which is the accepted **warm ischemia time** for the following organs:	As short as possible		No accepted stand	No accepted standard			No accepted standards: Use of clinical guidelines but up to med teams to accept or reject organs with long ischemia times
Liver		0				0	
Kidney		0				0	
Heart		0				0	
Lung		0				0	
Which is the accepted **cold ischemia time** for the following organs:	It depends on the tx centre that decides upon ischemia time and add.al all donor factors		These are "ideals" but often organ are transplanted with longer times. No nat.standards				No accepted standards: use of clinical guidelines but up to med teams to accept or reject organs with long ischemia times
Liver	12-16 hours	12 hours	12 hours	<20 hours		<12 hours	
Kidney	24-26 hours	48 h-max, mean 22 h	24 hours	<36 hours		24-36 hours	
Heart	4-8 hours	4 hours	4 hours max	<6 hours		<7 hours	
Lung	10-12 hours	6 hours	6-8 hours	<12 hours		<7 hours	

Donor Selection criteria:	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
The criteria for donor selection are regulated by:	No guidelines. The necessary tests for recipient safety that have to be done are laid down in an appendix to the contract of the DSO with the insurance companies, the German Hospital Foundation and the German Medical Association that was signed in 2000. The guide to quality and safety of the COE is paramount.	Law/guidelines (donor selection file)	Guidelines	Guidelines	Law/guidelines	Guidelines	Law/guidelines
If regulated who was in charge of the issuing?	Thus in charge of the issuing were the contracting partners. The contract was approved by the Ministry of Health. Furthermore the extended donor criteria can be found in the allocation guidelines of the German Medical Association.	Min. Health	MSBT: Dept. of Health Committee on the Microbiological Safety of Blood and Tissues for transplantation	Direcçao Geral de Saude, under the proposal of Nat Transplant Coord (OPT created in Oct 1996)	Ministry of Health, Tx Centres, Hungarotransplant	CNT	Min.Health-ONT
When were the regulations issued?	2000 (see text page 8)	Oct.9, 1997	2000	October 1995	Law 1997+further decrees	2003	Dec30 1999/Oct27, 1979
What kind of contraindications have been treated by regulation?		ESST/CJD VIH+, VHB+,VHC+(with exemptions)					
infections	No	Yes		Yes	Yes		
neoplasia	No	Yes: guidelines		No	No		
both		Yes	Yes			Yes	Yes

Which information do you collect from **donor medical history** for donor evaluation?	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
Anamnestic information available	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Risk factors for HIV/hepatitis	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Previous Infectious Diseases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Illicit substance abuse	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Neoplastic Diseases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Familiar history of malignancies	Yes	~~No~~Yes	Yes	Yes	No	Yes	Yes
Recent PSA value available (for patients with >50 years)	No	No	No	Yes	No	Yes	Yes
Surgical interventions	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Menstrual dysfunction	No	No	Yes	No	No	Yes	No
Pregnancy status	No	Yes	Yes	Yes	No	Yes	Yes
History of recent miscarriages	No	No	Yes	Yes	No	Yes	Yes
Cardiovascular diseases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pneumopathies	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Liver diseases	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Renal disorders	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diabetes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Autoimmune disorders	Yes	Yes	Yes	Yes	No	Yes	Yes
Hypertension	Yes	Yes	Yes	Yes	Yes	Yes	Yes
History of chronic dug use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dislipidemia	No	No	Yes	Yes	No	Yes	Yes
Alcohol consumption	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Smoking status	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diseases of unknown etiology	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Paediatric Donors	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
Exanthematic disease	No	No	Not specified	Yes	Yes	Yes	Yes
Mandatory absolute contraindications	known metastatic malignancy, fulminant sepsis, HTLV, HIV+, other viral infections (measles, rabies, adenovirus, enterovirus, parvovirus) prion-related disease, herpetic meningoencephalitis). Cases with previous hepatitis, HIV or malignancies are offered, tx doctors are free toaccept and inform recipient	AIDS/HIV+, Creutzfeld-Jacob, Meningo-encephalitis unexplained, rabies, disease of unknown etiol., active cancer	HIV, CJD	HIV1/2, HCV, HBsAg, Siphilis, HTLV, anti HBc(if anti-HBs neg)	Age >75 years Active TB HIV infection or positive serological or viral culture findings Jakob – Creutzfeld Disease HBsAg positive patient Anti-HCV positive patient Treated Malignancy (except primer cerebral tumor, basalioma and in situ portio carcinoma) Connective Tissue Disease Agranulocytosis Aplastic Anaemia Haemophilia	HIV+, contemp.HBsAg+/ HDV+, present malignant disease (except carcinoma in situ), systemic infections that do not respond to therapy, CJD	specified in attached guidelines
Relative contraindications	Rel contr. are numerous depending on recipient status	No list of rel contr	Sepsis, malignancy, neurotumours listed as high risk, risk behaviours from sexual or social history, viral infect, untreated bacterial infec, renal failure, disease of unknown etiol, neurodegen. disorders	Not specified	Organ-specific, final decision by surgeon	No list of rel contr, depends on recip.charact.	specified in attached guidelines

Tests required for Organ Donors:	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
Are the following **serological tests** carried out in organ donors?							
Anti HIV	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti HCV	Yes	Yes	Yes	Yes	Yes	Yes	Yes
HBsAg	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anti HBsAg	Yes	Yes	Yes	Yes	No	Yes	Yes: not mandatory but usually done
Anti HBcAg	Yes	Yes	Yes	Yes	No	Yes	Yes: not mandatory but usually done
HDV (if patients HBsAg positive)	No	No	Yes	No	No	Yes	Yes
Syphilis (TPHA/VDRL)	Yes	Yes	Yes	Yes	Yes	Yes: also possible after transplant	Yes: not mandatory but usually done
Anti CMV (IgG and IgM	Yes	Yes	Yes	Yes	Yes	Yes: also possible after transplant	Yes
HSV-1 (IgG)	No	No	Yes	No	No	Yes: also possible after transplant	No
HSV-2 (IgG)	No	No	Yes	No	No	Yes: also possible after transplant	No
EBV (anti VCA and anti-EBNA antibody)	Yes	Yes	Yes	Yes	No	Yes: also possible after transplant	No
VZV (IgG)	Yes	No	No	No	No	Yes: also possible after transplant	No
Toxoplasma (Antibody)	Yes	Yes	Yes	No	No	Yes: also possible after transplant	Yes: not mandatory but usually done
HTLV1/2		Yes					Yes: carried out in some emigrant donors

Are the following **routinary Instrumental tests** performed?	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
ECG	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Chest radiograph	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Echocardiography	No	~~No~~Yes	No	Yes	No	Yes: for heart donors alone	Yes: not mandatory but usually done
Abdominal and pelvic ultrasonographic examination	Yes	Yes	Yes: if abdominal path.suspected	Yes	No	Yes	Yes: not mandatory but usually done
Other		No	Yes: bronchoscopy for lung donors				
Which **tumour markers** are required for organ donors?							
BHCG	Dep on don char	No	Dep on don char	Dep on don char	Dep on don char	Dep on don char	Routine
PSA	Dep on don char	No	No	Dep on don char	Dep on don char	Dep on don char	Dep on don char
Carcinoembryonic antigen	Dep on don char	No	No	Dep on don char	Dep on don char	No	Dep on don char
Other							
If **positive PSA** do you perform transrectal ultrasonography?	No	No	No	No	No	Yes	Yes: Usually directly pathology analysis of the prostate
If **positive transrectal ultrasonography** do you perform biopsy?	No	No	No	No	No	Yes	Yes

	DSO	ABM	UKT	OPT	HUNGARO TRANSPLANT	CNT	ONT
Do you perform any test for **emerging disease**?	No	It depend on the epidemiological situation	No	No	No	No	Yes
West Nile							No
Rabies							No
Other							HTLV, Malaria
Do you have experts to turn to for a **second opinion** in doubtful cases?	Yes	No	No	No	No	Yes: national group	Yes: Hospital based
Histopathologist						X	X
Coroner						X	
Expert in Infectious Disease						X	X
Other	Every regional areas of the DSO is lead by an administrative medical director who is an expert in organ donation and transplantation						
Do they receive reimbursement for this assignment?	Yes					Yes	Yes: for pathology analysis and/or opinion

INFORMATIC ASPECTS	**DSO**	**ABM**	**UKT**	**OPT**	**HUNGARO TRANSPLANT**	**CNT**	**ONT**
IS for data of donors at risk of **infectious disease** transmission							
Is there a tool for expressing **second opinion**?	Yes	No	No	No	No	Yes	No
If Yes, please specify the features of the tool:							
Dedicated Information System						X	
Connected centres						3	
Utilized protocols (http, VPN, e-mail)						VPN	
Operative Systems						Windows	
Open Source or Commercial software						Commercial	
Authentication System for privacy needs						X	
Fax	X					X	
Connected centres or authorized experts						X	
Authentication System for privacy needs						X	
Telephone	X					X	
Connected centres or authorized experts						X	
Authentication System for privacy needs						X	
Video-conference						X	
Connected centres or authorized experts						X	
Authentication System for privacy needs						X	
Does the utilized information system allow a **data recording**?	Yes					Yes	
If **Yes** please specify the technical supports:							
Dedicated Information System	X						
Connected centres or authorized experts						X	
Utilized protocols (http, VPN, e-mail)							

	DSO	ABM	UKT	OPT	HUNGARO TRANSPLANT	CNT	ONT
Type of database	X					X	
Open Source or Commercial software						commercial	
Recorded information						X	
Authentication System for privacy needs						X	
Type of recorded information							
Clinical information						X	
Organizational information							
Other information						scanned histological images	
IS for data of donors at risk of **tumour** transmission							
Is there a tool for expressing second opinion?	Yes	No	No	No	No		No
If Yes, please specify the features of the tool:							
Dedicated Information System							
Connected centres							
Utilized protocols (http, VPN, e-mail)							
Operative Systems							
Open Source or Commercial software							
Authentication System for privacy needs							
Fax	X						
Connected centres or authorized experts							
Authentication System for privacy needs							
Telephone	X						
Connected centres or authorized experts							

	DSO	ABM	UKT	OPT	HUNGARO TRANSPLANT	CNT	ONT
Authentication System for privacy needs							
Video-conference							
Connected centres or authorized experts							
Authentication System for privacy needs							
Does the utilized information system allow a data recording?	X						
If Yes please specify the technical supports:							
Dedicated Information System	X						
Connected centres or authorized experts							
Utilized protocols (http, VPN, e-mail)							
Type of database	X						
Open Source or Commercial software							
Recorded information							
Authentication System for privacy needs							
Type of recorded information							
Clinical information							
Organizational information							
Other information							