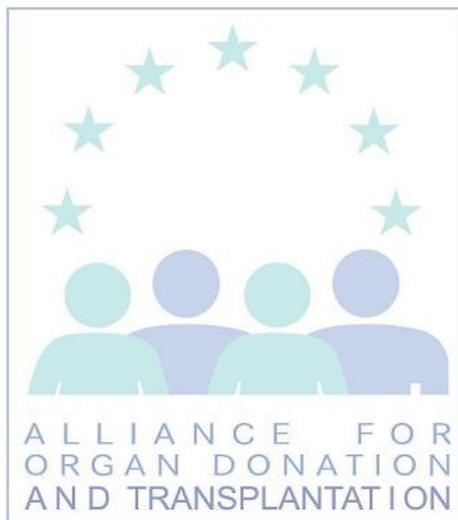


ERA-NET SCHEME
COORDINATION ACTION

ALLIANCE-O



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Work Package 7: Ethical and Legal Aspects

Deliverable 7. 2.: Position Paper

Work Package Leader: Deutsche Stiftung Organtransplantation

Participant name	Abbreviation	Country
Agence de la Biomédecine	ABM	France
Deutsche Stiftung Organtransplantation	DSO	Germany
Hungarotransplant	Hu-T	Hungary
Centro Nazionale Trapianti	CNT	Italy
Organização Portuguesa de Transplantação	OPT	Portugal
Organización Nacional de Trasplantes	ONT	Spain
UK Transplant	UKT	United Kingdom

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I. Introduction

The purpose of this Work package is to produce a position paper for the use of national and intergovernmental policy makers. In deliverable 7.1. legal and ethical difficulties in the field of organ donation and transplantation were identified and analysed. Based on the findings the working group elaborated the following conclusions and positions:

II. Upcoming EU legislation

In the light of the planned establishment of a basic quality and safety framework within the European Union the Alliance-O Group suggests a focus on the following aspects:

Ensure traceability and reporting of serious adverse events and reactions

Installation of registries that collect donor and recipient data.

Special attention is needed for Non-Heart-Beating-Donation or Donation after Cardiac Death (NHBD or DCD), extended criteria donor (ECD) and Living donors.

The Registries should be designed to allow for correlations between donor and recipient data (Donor risk index/recipient risk-levels) and ensure standardized post transplant care for all recipients and their follow up.

Confidentiality should be maintained in all cases.

II. Post mortem organ donation

1. Prerequisites for organ donation

There are two major prerequisites for post mortem organ donation:

No retrieval prior to certification of death.

No retrieval without consent of the donor or his next of kin.

The choice between the legal concept of presumed consent and informed consent is amongst others based on historical, social and cultural reasons. The detailed analysis revealed within the Alliance-O working group that the two concepts do not differ in day to day practice and that the family or next of kin must be in favour of donation in order to proceed with the donation process. A change of the legal framework therefore would not be a guarantee for an increase in donation rates.

2. Referral of the potential donor and refusal rate

The main task of all persons and institutions involved in organ donation is thus to increase consent rates within the legal framework. This can only be achieved by

raising public awareness of the necessity and advantages of organ donation and transplantation. The major focus must nevertheless be on the training of the personnel in charge of the family approach. When considering how to increase the organ donation rate a close look at the procedures in place to ensure the referral of all potential donors is required. It is undisputed that together with the consent rate the rate of referral of potential donors is one of the main factors influencing the donation rate in each country.

Appropriate policies need to be agreed and implemented to ensure that all potential donors are referred to the organ procurement organisation(s) (OPO) responsible for organ donation and procurement.

This requires the following tools:

Tool to evaluate the true donor potential.

Tool to monitor the referral and the performance of the hospital.

Tool to allow for referral of immanent death as soon as possible.

Only when policies are in place that ensure that all potential organ donors are referred to the OPO and consent rates maximised will a considerable increase in donation rates across the Europe be achieved.

The efficiency of the OPO's can be best expressed by the so called conversion rate. The conversion rate indicates how many potential donors¹ eventually become effective donors²

The goal therefore should be:

100 % Referral

85 % Conversion rate

3. Reimbursement of donor hospitals

A factor influencing the donation rate in this context is the appropriate/adequate reimbursement of the donor hospitals.

The participation of hospitals in organ donation must not be a disincentive activity. Reimbursement of all activities facilitating the organ donation process irrespective of whether it results in the retrieval of transplantable organs (futile donation) must be ensured.

¹ A potential donor is a deceased person without absolute medical contraindications with brain death diagnosis initiated or completed (Definition from DOPKI-Project).

² Deceased person, from which at least one solid organ was retrieved for transplantation purposes (Definition from DOPKI-Project).

4. Incentives for post mortem organ donation

So far in none of the participating countries incentives to the donor during their lifetime or to the family or next of kin are foreseen. Often quoted examples for such incentives are a reduction of taxes or health insurance in order to motivate individuals to express their consent to post mortem organ donation during their life time or to offer the family support towards funeral costs. Allowing for such incentives is a 'slippery slope' towards remuneration of post mortem donation. Therefore:

The Alliance-O group opposes to incentives to the donor or his next of kin for post mortem organ donation.

5. Non-resident-donors

In the context of consent to post mortem donation the group decided to take position regarding Non-resident-donors:

Organ donation from non-resident donors should be facilitated in each country according to national provisions. It needs to be ensured that if the deceased consented to donate, organs can be retrieved and transplanted in the country he died. To facilitate the recognition of consent to post mortem donation the diffusion of donor cards is recommended.

6. Minorities and Organ donation

It seems to be the case that certain ethnic or religious minorities are represented proportionally amongst the persons receiving a transplant however their representation on the donation side is disproportional.³ The group therefore suggests:

Specific initiatives to increase organ donation in specific ethnic minorities

7. Unconditional consent

In practice the wishes of the donor are respected as far as is reasonable and possible unless adherence of these wishes would result in a violation of law (e.g. organ trafficking).

**Allocation must follow national principles.
Discrimination of possible recipients must be prohibited.**

According to the legal provisions of the participating countries directed post mortem donation is prohibited. Neither the donor nor the relatives can choose the potential recipient of the donated organs. However practice shows that exceptions are required for exceptional cases.

³

Member states should define procedures on how to handle exceptional cases.

8. Non-Heart-Beating-Donation

Although NHBD or DCD is a possibility to increase the donation pool some of the participating countries are reluctant to introduce a NHBD program. Others like France only recently started with pilot programs. When enabling NHBD it is important to:

Introduce an appropriate (legal) framework for NHBD

Insure that this donor type is an add on and does not replace Heart-Beating-Donation.

Non-Heart-Beating-Donors are to be considered as multi-organ donors.

9. Quality and Safety

It is very difficult to determine the most appropriate time for tests and examinations evaluating donor suitability. Tests are mandatory in order to ensure the quality and safety of the organs transplanted. The right balance needs to be established through an adequate framework in order to:

Minimize the risks of transplantation for the recipient as far as possible without violating the donor rights at stake.

10. Extended Criteria Donor (ECD)

Due to the organ shortage and thanks to constant developments in transplantation medicine the use of ECDs is increasing. In order to benefit from the possibilities of expanding the donor pool with ECDs it is absolutely essential to:

Install a registry that collects donor and recipient data following transplantation of organs from ECDs and allows for correlation of this data. Such a registry must be based on a donor risk index and recipient risk levels.

Elaborate a common definition of ECD based on the data from the registry.

Transplant surgeons and physicians in charge of the recipient and follow up in this field need to be educated adequately in order to ensure that all centres are capable to use ECD.

Centre profiles should be publicly available and patients should be adequately informed about the possibilities of ECD. Informed consent of

patients registering for transplantation should include information about allocation rules and possibilities to receive ECD-organs.

and to ensure that also countries with limited experience in this field should procure ECD-organs as well.

11. Access of “Non – residents” to transplantation

In the view of globalisation and also the extension of the European Union to 27 member states

Access of non residents to transplantation medicine should be given due consideration in a European perspective, in order to be solved on a national level from a legal point of view. Any regulation should however be in accordance with national constitutions as well as European law (e.g. Art. 12, 18, 39, 43, 49 TEC and Council Regulation (EC) no 1408/71)

The best solution is prevention and to ensure the development of transplantation systems in all EU-member states and harmonise the donor rates by raising them to the highest possible level.

12. International organ exchange

Organ exchange across national borders outside the Eurotransplant region is limited due to the lack of surplus organs. Nevertheless

Cooperation should be facilitated for specific patient groups (children, high urgency patients, immunologically sensitive patients).

For this purpose the establishment of minimum quality and safety standards for international organ exchange is required.

13. “Double listing” and accounting for waiting time abroad

Not only organs move across borders but also patients in need of a transplant. In this context to ensure equity of access to transplantation:

Double listing in more than one national transplant system is avoided. In addition patients who relocate from one European country to another should be able to maintain their accrued waiting time.

III. Living donation

1. General principles

Living donation is an alternative to post mortem organ donation for certain organs such as kidney and liver:

There is a consensus that living donation must be on a non monetary and voluntary basis. Legal prerequisites need to be taken to ensure this as far as possible.

Living donation has potential health risks for the living donor and is only an alternative for certain types of organs. Therefore:

It should be ensured that post mortem donation is not neglected over living donation. Living donation must be an add on. The recipient should be offered the possibility of transplantation from a deceased donor when suitable organs are available.

2. Informed consent

The informed consent of a living donor must include the following aspects:

- Possible medical risks
- Side effects
- Necessary care afterwards
- Social, psychological and financial risks
- Alternative treatments for the recipient and success rate (individual recipient risk)

Sufficient information for this purpose should be collected in a:

Living donor registry that collects information on medical, social, psychological and financial effects and is part of the standardized follow up care for the living donor.