Workshop-Hearing
'Quality and Safety of Organ Donation and Transplantation'
Brussels, 19 November 2009

Proceedings

Abstract
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EXECUTIVE SUMMARY

This report summarises the presentations and discussions at a Workshop-Hearing on the Quality and Safety of Organ Donation and Transplantation, held at the European Parliament in Brussels on Thursday 19th November 2009. The aim of the workshop was to exchange views on the Commission’s 2008 proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation¹ and the associated Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States². Participants examined how to improve the quality of safety of human organs used for transplantation throughout the EU during all the phases of the process, including donation, procurement, testing, preservation, transport and use and.

The proposed Directive and the 10-point Action Plan are aimed at ensuring the provision of a basic level of quality and safety for all patients, and address three key challenges, namely improving quality and safety during all steps of the process, making transplantations systems more efficient and accessible, and increasing the availability of organs.

In welcoming participants, Dr Miroslav Mikolášik, MEP, Rapporteur for the Directive highlighted the aim of ensuring the quality and safety of human organs during the whole process from donation, procurement, testing, reservation, and transport to use. He outlined key elements of the proposed Directive that are intended at delivering a well regulated donation and transplantation system in all EU Member States, including the designation of competent national authorities and ensuring traceability.

Andrés Perelló Rodríguez, MEP, Rapporteur for the Action Plan, highlighted recent achievements in increasing donations within the Spanish system, noting that the higher number of donations can be largely attributed to a well functioning system. He stressed that the EU is characterized by a number of different legal and healthcare systems and the EU’s policies and legislative actions should reflect these differences and harness the existing levels of solidarity for donation.

Dr Andrzej Rys, DG SANCO, Health and Consumer Protection, provided a brief overview of where we stand today with respect to organ transplantation in Europe, noted that the situation is heterogeneous across Member States. He outlined how the proposal for the Directive and the Action Plan were adopted by the European Commission in 2008 to ensure the provision of a basic level of quality and safety for all patients. He discussed elements of the proposed Directive, including the establishment of national competent authorities, staff training programmes, national quality programmes, and traceability. He also outlined measures to ensure the protection of living donors, including the evaluation of donor health, information on risks, a register of donors, and ensuring that donations are voluntary and unpaid. Regarding the Action Plan, Dr Rys highlighted the introduction of transplant-coordinators in hospitals, raising public awareness and training, support for health professional working in the field, post transplant evaluation and a common accreditation system. In terms of possibilities for increasing cooperation between Member States, Dr Rys identified twinning projects and peer review, as well as the exchange of organs between Member States.

Dr. Enrique Terol García, Health and Consumer Advisor, Permanent Representation of Spain to the EU, outlined progress with the Directive in the Council under the Swedish Presidency and stated that the goal of the Spanish Presidency is to see the adoption of the Directive under their term. He highlighted two key messages, the importance of transparency and need for the improved cooperation between Member States. He expressed hope that the Directive will serve as an international reference, demonstrating good practices and effective systems with an emphasis on the issue of safety.

In discussion, participants addressed how to strike a balance between the requirements for data protection for both donors and patients and the need to ensure safety and traceability and to allow for the evaluation of transplant success linked to data on both patients and donors. They also considered the status of private organ procurement organisations under the proposed Directive, which states that such organisations should be public.

Dr. Rafael Matesanz, Director National Transplant Organisation (ONT), Madrid, Spain noted that transplantation is a very efficient medical technique and stressed that the rate of survival is constantly improving. He identified donor shortage as a universal problem, saying that the average donation rate in the EU was 18 donations per million inhabitants in 2008. Dr Matesanz went on to say that there still remains a long way to go on coordination and harmonisation between EU Member States, focusing on differences in organisational structure. Dr Matesanz explained how Spain has seen a threefold increase in the past 20 years from 14 to 36 donors per million (500 to 1500 donors) due to changes in infrastructure and the organisation. He highlighted the improvement of the intra-hospital chain as key to improving the organisation of the system, starting with a brain-dead individual, and including diagnosis, family consent, transfer and finally concluding with the transplant. He described the Spanish model for coordinating transplants. Dr Matesanz concluded by saying that the proposed Directive provides a good opportunity to establish an efficient structure and coordination system for 150 million people.

Dr. Alessandro Nanni Costa, Director of Italian National Transplant Centre, Rome, Italy, provided a practical picture of the transplantation process in Italy, looking at issues such as safety and quality, and highlighting the complexity of the system. He identified the different phases of a donation and transplantation process, including: donor identification; diagnosis; suitability assessment; consent; maintenance; allocation; waiting lists; transplant; and follow up. He stressed the need for continuous work to maintain training, reporting, continued education, staff sensitisation, the identification of responsibilities, and the assignment of tasks and activities. He noted that the identification of responsibilities and responsible authorities is critical to the whole process. Dr Nanni Costa identified donor and receiver management as the most important parts of the organ transplant process. He explained that in order to ensure quality, critical stages include: the transmission of documents from donor to reference centre; the decision of whether to use donor’s organ; and undertaking screening for the patient. He noted that post transplant follow-up in Italy includes the publication of data on the Health Ministry’s website regarding the results of transplants undertaken in each centre, serving to increase public trust and the credibility of the whole system. He said that the risk must be weighed up on a case-by-case basis, since organs may pose a risk due to a possible donor transmissible infection. He stressed that the patient must be consulted and agree in each case. Dr Nanni Costa identified the need for clear rules to frame decision-making in managing donations, to set parameters around which diseases to scan for, and to steer the risk analysis. He described the Italian system to assess risk known as “second opinion” and related monitoring systems.
Professor Dr med. Dr phil. Eckhard Nagel, Chief of the Surgery Centre and Transplantation Centre, Augsburg, Germany, focused on the social structures in Member States that affect organ transplantation. He stated that organ scarcity is not only a medical problem, but also a social problem as society has set itself the task to provide health care for all. In addition, he indicated that this generates another problem, since scarcity often results in abuse. He explained that in Germany, legal certainty, and a country-wide waiting list that provides for the equal evaluation of all patients, and transparency had improved conditions for transplantations. Dr Nagel expressed doubts that only organisational issues will be responsible for an increase in the availability of organs. He stated that a European-wide implementation of organ transplantation as a medical alternative requires an enormous investment, and these this not be covered by the supposed savings from transplantation. Regarding organ trafficking, he noted that public awareness, as well as the organisational structures, can curb and prevent it. He explained that the introduction of standards in Germany made it possible to improve the care for patients.

He pointed out that the differences in the Member States’ legislation for transplantation reveals a difference in the way we value the autonomy of an individual, and explained that when seeking improvements through standardisation these differences have to be taken into account. He also pointed to differences in financial resources across the EU. Dr Nagel also addressed tissue donation and living donation. He described how in Germany the question of allocating organs to patients is dealt with on the basis of success rate and urgency.

Håkan Hedman, Swedish Kidney Association, provided a personal picture of changes in kidney treatment over the past 50 years. He recounted his personal experience of being in hospital as a child, and receiving a kidney transplant. He noted the value of the present and expressed gratitude for his life and the treatment that he received. In terms of what can be done to improve the situation, he noted the need to remove legal obstacles to donation, to provide information to the public, increase information to health care personal and promote living donations. He also emphasised the need to facilitate living donations by ensuring for example that those who donate do not have to give up wages for the period over which they are incapacitated.

In discussion, participants addressed the issue of living donations, balancing transparency with the decision-making process for transplants, and immigrants’ access to transplants. They also considered education and public awareness raising, the transferability of structures and systems, and the illegal trade in organs.
1. INTRODUCTION


The hearing included high-level representatives from the European Commission and the upcoming Spanish Presidency, the presence of the Swedish Presidency, as well as a distinguished expert panel addressing best practices in Europe. It also featured the personal experience of a patient living with an organ transplant.

The aim of the workshop-hearing was to exchange views on the proposed Directive and Action Plan and to examine how to improve the quality of safety of human organs used for transplantation throughout the EU during all the phases of the process, including donation, procurement, testing, preservation, transport and use. The hearing also shed light on how the Directive and the Action Plan can facilitate cooperation between Member States.

Section 2 of this report includes a brief review of the policy background to the workshop-hearing, namely the proposed Directive and the Action Plan, and goes on to document the workshop proceedings in section 2. Summaries of all the presentations are included, as well as reports of subsequent question and answer sessions. Short biographies of the experts are provided in section 4. The workshop programme is included in Annex I and the power point presentations provided by the expert panel are included in Annex II.

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2. POLICY BACKGROUND

Thousands of patients in the EU receive treatments based on human biological substances donated by others: blood, tissues, cells, and whole human organs. Such substances are of high therapeutic value, but they may also carry risk for the recipient, in particular the transmission of communicable diseases.

The main challenge is the scarcity of human biological substances, in particular organs for transplantation. More than 50,000 patients are waiting for the donation of suitable organs in the EU and 12 of them die every day because organs are not available. There are major differences in rates of living and cadaveric organ donations between Member States and organ exchange is still not a common practice within the EU as a whole.

EU policies focus on three aspects of human biological substances – availability, safety and quality. These policies are coherent with international recommendations such as those of WHO and the Council of Europe.

The EU regulatory framework including requirements for safety and quality of blood and blood components, and for tissues and cells, have been developed and applied to a large extent by Member States. This framework defines minimum requirements and Member States can maintain or introduce national measures that are more stringent than requirements set by European legislation. There is no similar EU regulatory framework for organs in place as yet.

One of the goals of EU policy relating to human biological substances is to ensure European self-sufficiency. EU policy promotes donations but also emphasises that donations should be voluntary and unpaid. Procurement of human biological material regardless of whether it is carried out in the EU or in non-EU countries should respect human rights, dignity of donors and the non-commercial and non-profit character of donation.

In 2008, the Commission adopted the Action Plan on Organ Donation and Transplantation. The Action Plan focuses on increasing organ availability, enhancing the efficiency of transplantation systems and improving quality and safety. The priority actions are:

- Appointment of Transplant Donor Coordinators in each hospital and their training and coordination. In the future, development of transplant donor coordinator programmes, with standards and accreditation of transplant donor coordinators is envisioned;
- Quality Improvement Programmes for organ donation should be implemented in all hospitals with potential for organ donation;
- Promotion of exchange of best practice on living organ donation programmes;
- Improvement of the knowledge and communication skills of health professionals and patient support groups on organ transplantation;
- Facilitation of identification of suitable organ donors across Europe and cross-border donation in the EU;
- Enhancement of the efficiency of national transplant systems in Member States;
- Establishment of the organ exchange system for urgent and difficult-to-treat patients and a system for exchange of surplus organs. This includes the development of an IT tool to support these exchange systems;
- EU-wide agreements on various aspects of transplant medicine;
- Establishment of registers for evaluations of post-transplant results. These will facilitate the development of good medical practices in organ donation and transplantation;
- Building a common accreditation system for organ donation/procurement and transplantation programmes, and providing support for centres of excellence.

In 2008, the Commission proposed that the European Parliament and the Council adopt a directive on standards of quality and safety for human organs intended for transplantation. This draft directive sets out the following requirements for Member States:
• Member States should establish national quality programmes to cover all stages from donation to transplantation;
• Member States ensure that organ procurement takes place in procurement organisations. Procurement organisations must carry out procurement in dedicated facilities under conditions that minimise bacterial or other contamination and which comply with standards for operating theatres;
• Medical activities of procurement organisations are performed under the supervision of a medical doctor;
• All procured organs and donors are characterised before transplantation through the collection of the prescribed data. The tests required for organ characterisation should be carried out by a qualified laboratory;
• Organisations involved in transport of organs must have in place appropriate standard operating procedures to ensure the integrity of organs during transport, minimal transport time and the required labelling;
• Transplantation centres have to be accredited by a competent authority.
• Transplantation centres must verify organ and donor characterisation, and transport and storage conditions before proceeding to transplantation;
• Member States have to ensure full traceability through all stages from the donor to the recipient and vice versa. Data is kept for a minimum 30 years;
• A reporting system for serious adverse events and reactions should be in place. The system must enable rapid recall of organs related to adverse events or reactions;
• Member States must ensure that donation of organs from deceased or living donors are voluntary and unpaid and procurement of organs is carried out on a non-profit basis. Advertising of donation that offers or seeks financial gain is prohibited. Mandatory consent or authorisation requirements must be respected;
• Living donors have to receive all information necessary to make an informed decision prior to the donation. Suitability of the donor is evaluated on the basis of health history by qualified professionals. Competent authorities keep registers of living donors and follow-ups of donations.
• Personal data of donors and recipients must be protected in all organ procurement and transplantation activities;
• Member States designate competent authorities that enforce the requirements set for organ procurement organisations and transplantation centres;
• Exchange of organs with third countries is only allowed if it is approved by a competent authority and if organs meet quality and safety requirements equivalent to European requirements.
• Member States can establish agreements with European organ exchange organisations provided they meet specified requirements.
3. PROCEEDINGS OF THE WORKSHOP-HEARING

3.1 Panel 1 - Policy and institutional representatives

3.1.1 Welcome and opening – Dr Miroslav Mikolášik, MEP, Rapporteur for the Directive

Dr Mikolášik welcomed all participants, stressing the importance of the meeting and its aim to ensure quality and safety of human organs during the whole process from donation, procurement, testing, reservation, and transport to use. At the same time, he noted that participants would discuss how to achieve the common goal to increase the availability of organs. Dr Mikolášik stressed that these goals can be achieved through a well regulated donation and transplantation system in all EU Member States. He noted that the proposed Directive makes provisions for the designation of a competent national authority in each Member State and will ensure quality via national quality programmes, stating that this will ensure standards in managing the donation process and facilitate the cross-border exchange of organs. He explained that the Directive also establishes systems that allow all organs to be traced from donation to reception, stressing that, while respecting the principles of confidentiality, traceability is an important factor in reducing trafficking. He noted that in a context where there is a principle of unpaid and voluntary donations, as under international legal standards, the protection of donors is important. He concluded by inviting everybody to share their views on these issues before the legislation process goes ahead.

3.1.2 Welcome and opening – Andrés Perelló Rodríguez, MEP, Rapporteur for the Action Plan

Mr Perelló provided a brief overview of the Spanish system. He noted that although the number of organ donations in Spain is higher than in other EU Member States, this does not necessarily imply that Spanish people have a more developed sense of solidarity than other people. Given the fact that the willingness to donate an organ is higher in some other countries, he said that the higher number of donations can be largely attributed to a well functioning system. Spain managed to increase the number of donations from 14 per million to 34 per million since the introduction of the system. However, Mr Perelló stressed that it would not be feasible to directly transfer the Spanish system to other countries. He emphasized the fact that the EU is characterized by a number of different legal and healthcare systems and the EU’s policies and legislative actions should reflect these differences and harness the existing levels of solidarity for donation. He noted that the logical outcome of a better organ transplantation process could be synthesized by the slogan ‘more life’. Mr Perelló highlighted the need to obtain the Parliament’s consensus and approval of the proposed Directive.
3.1.3 The EU's efforts to provide high quality and safe transplantation systems, Dr Andrzej Rys, DG SANCO, Health and Consumer Protection

Dr Rys provided a brief overview of where we stand today with respect to organ transplantation in Europe. He explained that currently 56,000 patients are waiting for an organ in the EU and that of these patients more than 5,500 patients die every year waiting (figures of 2006). He noted that the situation is very heterogeneous across Member States, with varying levels of donations. Some Member States rely on domestic sources, while others have set up multi-national systems.

Dr Rys outlined how the proposal for the Directive and the Action Plan were adopted by the European Commission in 2008 to ensure the provision of a basic level of quality and safety for all patients by improving quality and safety at all steps of the process, making transplantations systems more efficient and accessible, and increasing organ availability. He explained that the proposed Directive will ensure the establishment of national competent authorities, staff training programmes and national quality programmes, noting that the latter should ensure progress monitoring and the development of good practices.

He continued to explain that Member States are also asked to ensure the traceability of each organ, based upon a common set of characteristics for each organ, in order to allow transplant teams to make fully informed decisions whether to use an organ or not. He noted that there are also a number of measures to ensure the protection of living donors, such as the correct evaluation of donor health, comprehensive information on risks and a register of donors to follow up their status. He emphasised that the unpaid and voluntary nature of a donation is an important part of the proposal, saying that all member States shall ensure that donations are voluntary and unpaid. Overall, he stressed that the proposal allows Members States to adopt a system that is suitable to their own requirements and systems.

Dr Rys noted that the Action plan introduces ten priority actions to ensure better cooperation between Member States in managing organ donations and transplants. Firstly, the Action Plan promotes the introduction of transplant-coordinators in hospitals, which Dr Rys identified as a key element in improving organ availability in Spain. Additional steps flagged by Dr Rys include raising public awareness and training and support for health professional working in the field. He indicated that Member States may also opt for a living donation programme to complement the use of organs from cadavers. Other possibilities for increasing cooperation between Member States identified by Dr Rys included twinning projects and peer review, as well as the exchange of organs between Member States. He stressed that the Action Plan will complement the proposed Directive by evaluating post transplant results and establishing a common accreditation system. Finally, with respect to the implementation of the Action Plan, there is a specific timeframe for addressing each priority, with the set up of coordinators currently in progress and a set of evaluation indicators under developed.

Dr Rys indicated that the proposed Directive has so far received support from the European Economic and Social Committee (EESC), and that first readings have been held in the Council. He highlighted a strong commitment to passing the Directive in the Council during the Spanish presidency before the end of June.
3.1.4 Message from the Spanish Presidency, Dr. Enrique Terol García, Health and Consumer Advisor, Permanent Representation of Spain to the EU

Dr Garcia indicated that the proposed Directive has been examined in the Council during the last presidency and there will be two more meetings in December, which should make it possible to scrutinize the entire text. Dr Garcia credited the Swedish presidency with boosting the legislative process and granting Spain an active role. He stated that the goal of the Spanish Presidency is to see the adoption of the Directive under their term. He highlighted two key messages, the importance of transparency and need for the improved cooperation between Member States. He expressed hope that the Directive will serve as an international reference, demonstrating good practices and effective systems with an emphasis on the issue of safety.

3.1.5 Discussion

Question 1:

H. Kranenborg, representative of the European Data Protection Supervisor, stressed that organ donation is also about the exchange of personal data, and noted the reference in the proposed Directive to the Directive on Data Protection. He stressed, however, that anonymity is not compatible with traceability, and that data protection rules require certain security measures. He stated that it would be relevant to consider a provision focused on the harmonisation of security measures stemming from data protection legislation.

Responses:

Dr Terol Garcia recognised that this is a very important issue, stating that both donors and recipients need to have their data protected. However, he indicated that ensuring quality requires traceability.

Dr Rys noted that the Commission would like to address this issue, but had uncertainties regarding how to implement it in practice. He said that Member States’ competent authorities have to address data protection and put technical systems in place to ensure the protection of all personal data. He expressed hope that experiences could be shared as to how the two goals of traceability and data protection can be achieved.

Dr Mikolášik mentioned that he will use his position as rapporteur that certain ideas and principles are implemented to ensure the best protection of data for patients and donors.

Question 2:

Dr. Michalski, Brussels University, stated that safety in organ transplants is based on the training level of staff, and noted that few Member States actually have specialised transplantation training. He stressed that it is important for the success of the Action Plan to develop an education programme to ensure the supply of specialists in the member States.
Responses:

**Dr Rys** said that this was discussed in the Green Paper on Health Care Professionals, where the set up of an Erasmus programme was discussed under which health professionals can travel to other countries for six months to learn and gather experience. He expressed hope that there will be ongoing support in the budget for this kind of programme. He noted that there will be other specialities taken up into this programme and said that organ transplantation could be used as a pilot programme.

**Question 3:**

**Dr Kirste, German Procurèrent Organisation**, noted how important it is to combine the success rate of transplants with the data from the patient side. He stressed that doctors need this data to move forward with assessing the success and performance of transplants and questioned how this need can balance with data protection. In addition, he explained that the Directive states that procurement organisations should be public government organisations, whereas in some countries they already have a private status. He asked whether it is foreseen that procurement organisations may have a private status.

Responses:

**Dr Rys** agreed a performance based system needs data, and noted that this will be addressed under the Annexes to the Directive. With regards to the second question, he noted that the aim is not to change what already works in Member States, but rather to increase donations and make more organs available.

**Dr Terol Garcia** said that this question had been discussed in the Council, and said the aim was to improve the current system without harming organisations that are running well. He stressed the need to respect both transnational and national bodies in the Member States.

**Question 4.**

**Arie Oosterlee, EuroTransplant International Foundation**, noted that his organisation supports the purpose of the proposed Directive in improving national programmes and ensuring that countries become self sufficient in organ donation. He highlighted the importance of follow up data in ensuring accountability and managing risks. He asked whether there are plans to make a recommendation or make it obligatory to collect data on performance linked to donor patient criteria.

Responses:

**Dr Rys** said that this is included in the Action Plan, and said that a step by step approach is required to develop requirements for data management. He noted that it is always difficult to include obligatory measures due to the need to reach consensus amongst all 27 Member States. He said that the Commission is adopting a softer approach, but that he would take this on board as a proposal.
Dr Terol Garcia said there is a need for balance between the capacities of the Member States and respecting data confidentiality and stressed the need to work cooperatively.

3.2 Panel 2 - Distinguished Experts and patient representative on best practices in Europe on organ donation and transplant

3.2.1 Dr. Rafael Matesanz, Director National Transplant Organisation (ONT), Madrid, Spain

Dr Rafael Matesanz noted that transplantation is a very efficient medical technique, with over 100,000 transplants undertaken all over the world every year, including inter-alia kidney (around two third of the transplants), heart, lung, and liver transplants. He stressed that the rate of survival is constantly improving, citing the following survival rates, 45 years for the kidney, 40 years for liver and 30 years for heart transplants.

He identified donor shortage as a universal problem, in a context where one million patients could benefit from a transplant if there were sufficient organs, hospitals, doctors, and resources, while less than 10% actually do receive a transplant. He said that no less than twelve people die per day in the EU because they cannot get a transplant, stressing that this will increase due to the increasing propensity of diabetes, as well as aging, hypertension and obesity.

Dr Matesanz indicated that in the EU in 2008, there were 8000 donors, 30,000 transplants and 70,000 people waiting for transplants. He said that the average donation rate in the EU is 18 donations per million inhabitants in 2008, noting that this is lower than the US (26.3 per million), and Spain (34-35 per million). He noted that in undertaking to increase the donation rates, the US had changes similar to those in the Action Plan resulting in a significant increase in donations.

He explained that during the 1990ies and at the beginning of the 2000ies, a lot of work was undertaken on coordination systems for transplants by the Council of Europe. He noted that the Transplant Commission of the Council of Europe has collected a lot of data (relating to donations, transplants, cells, tissues) and has issued safety guides and 14 recommendations on transplant matters, one of which “Meeting the Organ Shortage” is a cornerstone document and the basis of the Directive proposal discussed today.

Dr Matesanz went on to say that there still remains a long way to go on coordination and harmonisation between EU Member States, highlighting considerable differences in the law across the EU (For example on the consent of the donor and the type of donors allowed). He focused on differences in organisational structure, saying that countries like France, Italy, UK, and Spain have very strong organisational structures, while other countries do not have the necessary national bodies and organisational structure to underpin existing organ transplant activities. He noted that donation rates within EU Member States vary from 1-34 organ donors per million, stressing the need to change the situation to provide more equity between European citizens.

Regarding the issue of living donors, which is also covered by the Action plan and the proposed Directive, he indicated that this varies depending on the country, with the system being more developed in Scandinavia, UK, and Germany than in Southern European countries.

He noted that thanks to several EU level projects focusing on harmonisation, a good collection of data on practices in the Member States has been established. For example, Dr Matesanz explained that epidemiological data varies between countries regarding the cause of death of donors, i.e. cardiovascular versus brain death. He indicated that there is also better knowledge of the distribution by age of donors in the different countries of the EU.

Dr Matesanz explained how Spain has seen a threefold increase in the past 20 years from 14 to 36 donors per million (500 to 1500 donors). He stressed that the attitudes of the Spanish population towards organ donation have not changed, with the percentage that would donate having remained relatively constant (58% twenty years ago, 56% in the nineties and 58% nowadays). He indicated that it was the infrastructure and the organisation that changed, stressing that there is no link between the pre-disposition of the population to donate and the number of donors, but rather that it is the efficiency and effectiveness of the system that impacts on the number of donors.

He highlighted the improvement of the intra-hospital chain as key to improving the organisation of the system, staring with a brain-dead individual, and including diagnosis, family consent, transfer and finally concluding with the transplant. Dr Matesanz explained how the Spanish coordination network was set up in 1989, stating how for a country of 46 million people it has transplant coordination teams in 167 hospitals, 224 doctors involved (75% working part-time on transplant issues, 4% dedicated to coordination) and 129 nurses. He described how the Spanish model is characterised by a three-tiered coordination network (national level, autonomous communities’ level and hospital level), and highlighted high quality reporting on the potential for donation, adequate financing, an emphasis on professional training and good media attention. He emphasised the importance of a coordination system in promoting change by increasing transplants, citing the example of Rioja, where the rate of donors increased from 3 per million to 74 per million people following the introduction of a coordination system.

Dr Matesanz went on to emphasise the need for cost effectiveness, stating that there is a higher survival rate and quality of life with kidney transplants, which are cost effective if compared to dialysis in the long term thus leading to both an improvement in the quality of life of patients, as well as savings in the costs of treatment.

Dr Matesanz concluded by saying that the proposed Directive provides a good opportunity to establish an efficient structure and coordination system for 150 million people, that could work better than the one put in place in United States and achieve rates of 30 donors per million. He stated that it is therefore important to work collaboratively to achieve this goal and effectively double the number of patients receiving transplants in the EU.
3.2.2 Dr. Alessandro Nanni Costa, Director of Italian National Transplant Centre, Rome, Italy

Dr Nanni Costa began his presentation by noting that the 1999 Italian legislation on organ transplant has had positive effects in the national context. He stressed that it is strongly desirable to launch the European legislative action as soon as possible in order to have the whole EU system to develop in a similar way. He provided a practical picture, looking at issues such as safety and quality, and highlighting the complexity of the system. He identified the different phases of a donation and transplantation process, including: donor identification; diagnosis; suitability assessment; consent; maintenance; allocation; waiting lists; transplant; and follow up.

To ensure safety and quality, he stressed the need for continuous work to maintain training, reporting, continued education, staff sensitisation, the identification of responsibilities, and the assignment of tasks and activities. He noted that the identification of responsibilities and responsible authorities is critical to the whole process. In this regard, he suggested that there is the need for a set of rules with little margin of discretion for the Member States, stating that this is achieved through the Transplant Information System in Italy, involving multiple actors and stakeholders.

Dr Nanni Costa identified donor and receiver management as the most important parts of the organ transplant process. He explained that donor management is a multi-stage clinical and logistical process involving key decisions to identify the right donor and assess the balance of life between the donor and recipient.

He stressed that every intensive care unit should have a register in order to ensure quality, transparency and dynamism when identifying possible donors, saying that this would facilitate each step of the donation and transplantation process. He explained that in order to ensure quality, critical stages include: the transmission of documents from donor to reference centre; the decision of whether to use donor’s organ; and undertaking screening for the patient. Dr Nanni Costa explained that the multiple stages and individuals in the network demand collaboration and open exchange of information.

Regarding the management process for receiving organs, Dr Nanni Costa stated that it is possible to define the organs as public goods, generating the requirement for transparency and quality. He noted that post transplant follow-up in Italy includes the publication of data on the Health Ministry’s website regarding the results of transplants undertaken in each centre. He explained that publishing data on survival rates in different of transplant centres increases public trust and the credibility of the whole system, with a consequent increase in the number of potential donors.

Dr Nanni Costa explained that the shortage of donors has stimulated the development of strategies to allow procurement of organs from additional donors, stressing that the criteria for accepting an organ are not absolute but rather depends on the capacity of the patient to accept an organ and the expected life span of the patient. He said that the risk must be weighed up on a case-by-case basis, since organs may pose a risk due to a possible donor transmissible infection. He stressed that the patient must be consulted and agree in each case.
Regarding, the possibility of donor transmissible infection, Dr Nanni Costa identified the need for a clear rules to frame decision-making in managing donations, to set parameters around which diseases to scan for, and to steer the risk analysis. He stressed that the decision to undertake a transplant needs to be quick and effective, recognizing the existence of an unavoidable level of risk. He explained that guidelines should address five risk levels: acceptable risk; increased but acceptable risk; calculated risk; not assessable risk; and standard risk. He described the Italian system to assess risk known as “second opinion”, a complex system governing the dynamic process of decision-making in organ transplants. He explained how a monitoring system has increased the capacity to detect tumours in organs prior to transplant and prevent the transplantation of organs with tumours. He identified the need for common rules to ensure that Member States operating best practice can contribute to making the EU system more robust.

In conclusion, Dr Nanni Costa noted that organ transplants extend life expectancy and can dramatically improve quality of life. He stressed that the balance between the risks associated with an organ and the benefit to the patient require a systematic management of the screening process for donors in order to ensure quality and safety.

3.2.3 Professor Dr med. Dr phil. Eckhard Nagel, Chief of the Surgery Centre and Transplantation Centre, Augsburg, Germany

Dr Nagel indicated that his presentation would focus on the social structures in Member States that affect organ transplantation. He explained that organ transplantation is a fundamental achievement for the individual, as well as for society as a whole. He stressed the need to raise the question of why transplants are only available for some people and why there are still many people dying every day while waiting for a transplant. He stated that this is not only a medical problem, but also a social problem as society has set itself the task to provide health care for all. In addition, he indicated that this generates another problem, since scarcity often results in abuse. He noted that although this does not happen in Europe, it is a problem in many parts of the world that organs are paid for or there is associated abuse of the individual.

He explained that in Germany, organ transplantation developed without any strong legislative framework. Rather, he explained that the spirit of research and cooperation drove the development of organ transplantation during the 1990ies. He stated that it came to a point where the problems of selecting recipients and cases of abuse made it necessary to develop legal structures, resulting in fundamental improvements for citizens. He highlighted legal certainty, and a country-wide waiting list that provides for the equal evaluation of all patients, raising the question of whether the same access and evaluation could be provided to all EU citizens. He highlighted another achievement secured by the German legislation, namely total transparency, saying that there is no other medical area where there is so much results-related data available.

Dr Nagel raised the following questions: What are the goals that are related to the activities of the European Institutions? Can the proposed activities actually achieve these very comprehensive goals? And is it possible to increase organ donation through the proposed activities? Noting that if the Spanish assessment that only organisational issues are responsible for an improvement in organ donation were correct, this would be easy to answer. However, Dr Nagel expressed doubts that only organisational issues will be responsible for an increase in the availability of organs.
Regarding the set up of efficient organisational structures necessary to offer organ transplantation as an alternative to patients, Dr Nagel stated that a European-wide implementation of organ transplantation as a medical alternative requires an enormous investment, and these this not be covered by the supposed savings from transplantation (i.e. from kidney transplantation versus dialysis).

Dr Nagel noted that public awareness, as well as the organisational structures, can curb and prevent organ trafficking, saying that if organ trafficking is not prevented then it will be very difficult to fully accept organ transplantation.

With respect to an improvement of security and quality through transparency, he stated that Germany can, like Spain and Italy, function as a model. He explained that the introduction of standards made it possible to improve the care for patients. He pointed out that the differences in the Member States’ legislation for transplantation reveals a difference in the way we value the autonomy of an individual, and explained that when seeking improvements through standardisation these differences have to be taken into account. As a valid precondition for organ donation, he stressed the need for a clear EU-wide regulation that defines cerebral death and respects it as the death of an individual and that sets out clear procedures.

Dr Nagel addressed the equal distribution of resources, noting that the different health systems in Europe have very different approaches to equal access and distribution and it is questionable as to whether these can be standardised with respect to organ.

Regarding tissue transplantation, Dr Nagel explained that in Germany the donation of organs and tissues are regulated through different laws. He stressed that if tissue is not seen as an essentially intangible good that can only be passed on through voluntary donation, this will result in a commercialisation of the human body and making it impossible to prevent organ trafficking.

He considered the ethical questions surrounding living donations, citing immense differences in the use of living donations in Europe that result from differences in the admissibility of these procedures. He stressed the need to consider the admissibility and security of living donations.

He explained that in Germany there is a great resistance to regulating organ donation through assumed consent, generating the need to look at the issue of how to distribute the available organs to the waiting patients and how to explain to the family of the patient why their relative was not selected for transplantation. He described how in Germany this question is dealt with on the basis of success rate and urgency. However, he noted that the question of what constitutes success is not absolutely solved but rather relates to security and quality. He emphasised the importance of financial investment, noting that investment in one area will cut resources for another.
3.2.4 A Patient’s story: living with an organ transplant – Håkan Hedman, Swedish Kidney Association

Mr Hedman, Swedish Kidney Association, stated that as a representative of patients, the Swedish Kidney Association distances itself from commercial trading in organs. He recognised the efforts within Spain regarding organ donation, noting that Sweden used to have a higher number of donors per million that Spain but has subsequently been overtaken. He stated that he received a kidney himself 25 years ago and noted that he has 50 years of perspective on the system of organ donation. He went on to provide a personal picture of changes in kidney treatment over the past 50 years.

With reference to pictures from a Swedish hospital in the 1960ies, he identified a number of children that in 1961 had died of various diseases, but who today would have been able to have transplants and survive. He recounted his personal experience of being in hospital as a child, at a time when parents were not allowed to visit their children for more than three hours a day. He explained how his first transplant was rejected by his body and he received dialysis treatment for 9 years. He described how he then received a kidney from Brussels and has been very happy with the results. He explained that he was unable to do sport prior to the operation, but set a personal goal of undertaking sporting activities after receiving his new kidney and has subsequently participated in the World Transplant Games. He noted the value of the present and expressed gratitude for his life and the treatment that he received. He stressed that he is not dependent on dialysis and that he is independent, working full-time and has a family. With regards to dialysis treatment, he noted that 80% of patient undergoing dialysis in Sweden suffer chronic dialysis and do not receive transplants. He stressed the importance of Erythropoietin (ERP).

In terms of what can be done to improve the situation, he noted the need to remove legal obstacles to transplants in order to allow those who want to donate to do so. He also stressed the need to provide information to the public, increase information to healthcare personal and promote living donations. He also emphasised the need to facilitate living donations by ensuring for example that those who donate do not have to give up wages for the period over which they are incapacitated. He recognised the need for a functioning system to promote organ donation, including patient organisations, above making changes in the public willingness to donate.

3.2.5 Questions and answer session

Question 1:

Roberto Tyresy, President of Belgian Transplant Society, identified the need for efforts to improve living donations, but said there is a need to consider that resources are limited and there will always be inter- and intra-national differences in organ donation. He said that it would be important to consider the aspect of living donors in the proposed Directive and to ensure the protection of living donors. He identified possibilities to improve living donation, for example the reimbursing of hospital costs and post-operative cost.
Responses:

Dr Costa responded that deceased donors represent the bulk of donors (80-90%). He agreed that the ethical issues need to be resolved with regards to living donors, saying that if the right conditions are in place, a living donor may be relevant. He stressed that it is not always easy to draw a line between living organs and the vulnerability of people who may be immigrants and sell their organs. While he agreed that the issue of living donors must be included in the Directive to provide an equal set of rules, he noted that the Directive focussed on deceased donors due to the prevalence of this source.

Dr Nagel recognised the ethical complexity of living donations, and stressed that people also have a right to donate, for example a parent to their child. He raised the question of whether living donations should be made between individuals who do not know one another, noting that in the US it is possible to make an anonymous donation in order to provide assistance to another. He highlighted the problem of people donating organs due to their economic circumstances and the instrumentalisation of the human body through the criminal organ trade. He stressed the need to exclude this latter scenario from the EU context.

Question 2: Mr Correia de Campos, MEP Portugal, described Portuguese legislative developments on organ transfers, noting that a negative campaign had been launched against the law, and was subsequently discovered to have been organised by the kidney dialysis industry. He noted there were also questions regarding the technical capacity of the country to conduct transplants, and raised the question of the allocation of available funds between different public health priorities. He stated that in Portugal the method chosen to generate funds was quite instrumental, allowing public service doctors and health care practitioners to participate in transplants. He raised a question regarding the medical criteria for transplants, chances of success and priority, asking how the decisions making process can be combined with total transparency.

Responses:

Dr Nagel noted that, in Italy as well as in the USA and Germany, the results of transplant operations are published in the internet. He questioned whether that represented full transparency, or whether there is a need for interpretation to understand how badly ill the patient was relative to the success rate. He therefore stated that there is no sufficient transparency. He explained that in Germany, the criteria for someone to join the waiting list is published and can be researched, as well as the death rate of people on the waiting list and comparative data with other Member States. He concluded that transparency regarding the individual cases cannot be realised since it contradicts the patient’s privacy.

Question 3:

Luz Cardona Canales, World Youth Alliance, asked whether people who died of euthanasia can be used for an organ donation. She questioned whether this procedure still be ethical and transparent? She also asked how immigrants are taken into account in the Directive and the Action Plan, or whether extends only to EU citizens?
**Responses:**

**Dr Costa** said that transparency is important in increasing public trust. He noted that a wide range of data on the waiting list, the criteria for putting people on the waiting list, is published in Italy. He stressed that it is not easy to measure the results of specific physicians, but at the hospital level this data can be measured. He said that the Directive will make it easier to measure, but not at the level of the individual patient. Regarding immigrants, he recognised that they are both donors and patients. He noted that having an EU standard will help us but that we must recognise the ethical problem and the difficulty of extending the possibility of organ transplants to all in a context where donated organs are limited.

**Dr Matesanz** noted that the legislation varies between Member States, saying that in Spain residents have the same access to organ transplants as citizens. He stressed that transplant tourism (patients travelling between countries to receive transplants) is banned. On a separate issue, he noted that the concept of euthanasia is not related to brain death.

**Dr Nagel** spoke on the issue of euthanasia, stressing that the brain death criterion is supplemented by the possibility of taking organs after cardiac death. He noted that in Germany this is not possible and called for a discussion on the issue of defining brain death and cardiac death.

**Question 4:**

**Dr Kirste, German Procurèrent Organisation,** noted that while the organisational structure is very important, we have huge differences between the Member States. He said that it is not possible to transfer the Spanish system to other Member States, due to different medical infrastructure, meaning there will still be differences in the availability of organs in each Member States. Given the possibility of patient movement, he asked how this problem could be addressed.

**Responses:**

**Dr Matesanz** agreed that there are considerable differences between Member States, but noted that some aspects, such as hospital coordinators, can be transferred. He stressed the need to look at common and different factors across Member States under the Action Plan.

**Question 5: Wishing Young, NTV Chinese Language TV,** highlighted the forceful harvesting of organs from members of the Falon Gong community in China, and asked how the Directive seeks to ensure the elimination of organs sourced through illegal activities. He enquired whether the Commission seeks to prevent transplant tourism to countries like China.

**Responses:**

**Dr Rys** responded that the Commission is seeking to ensure that there is no avenue through which illegally harvested organs can enter the European system. He stressed that the proposed Directive is not just about the EU, but also about how the system can help other countries. He noted that the Commission is collaborating with EUROPOL to understand the illegal trade.
Dr Nagel noted that in most countries there is clear transplant legislation implying that illegal organ harvesting is a crime. However, he said that in China there is a different perception of the human and that legal procedures do not give the same level of protection to the individual as would be expected in the EU. He stressed that these issues must be settled in the UN.

Dr Mikolasik stated that in 2005 the European Parliament had heavily condemned the abuse of the poverty of women in Romania who were paid to provide ova, noting that the trade was subsequently stopped. The European Parliament reacted to the alleged case of commercial trade in human egg cells by a clinic in Romania by issuing a resolution, and called for measures to investigate whether such trade exists within the EU and stop it. The EP considers paid donation of eggs cells as exploitation of women.

Dr Rys questioned how parents should introduce the topic of organ donation to their children.

Dr Nagel stated that it is a duty to speak about organ donations with young people, since organ transplants are part of the medical system. He noted that in Germany, efforts have been made to integrate this into the school curriculum, as well as encouraging families to discuss the issues.

Dr Costa mentioned that importance of traceability in eliminating the illegal organ trade and ensuring that security and legality of organs. He stressed the importance of trust in securing the system and raising public awareness in allowing people to make informed choices as to whether to donate. He noted the role of the European Parliament in creating a space to discuss the issue and raise awareness and think about possible options and guidelines for governments.

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6 European Parliament resolution of 10 March 2005 on the trade in human egg cells
4. SHORT BIOGRAPHIES OF EXPERTS

**Allessandro Nanni Costa**
Director of the Italian National Transplant Centre, Rome.

In 1979 Dr Nanni Costa got a degree in Medicine at Bologna University, and got later masters in Nephrology and Immunology. He has been working in the field of research on organ transplantation since 1980 and is the author of about 200 papers. He has also trained in the field of Immunogenetic and in transplant activities. From 1980 to 1996 he worked at Sant’Orsola Hospital in Bologna. Since 1985 he has been in charge of the main educational programmes for transplant co-coordinators in Italy. From 1997 to 1999 he was the Regional Coordinator of donations for Emilia-Romagna and general manager of the Hospital Service at the Health Regional Department of that same region. In February 2000, he was appointed as general director of the Italian National Transplant Centre (CNT), developing the following activities

- Coordinator of the EURODONOR project mainly based on the development of a database and portal for delivering update information on donation and transplantation in Europe.
- Member of the Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation of the Council of Europe as Italian representative;
- Chairman of EU Expert meeting on Safety and Quality in Organ Donation and Transplantation, Venice, 17-18 September 2003
- Chief Editor of *Organ and Tissue*, an international journal dedicated to organ and tissue donation and transplantation published since 1997
- Chairman of national and international Course of transplant coordinator education in cooperation with University of Barcelona and University of San Marino

**Dr. Rafael Matesanz**
Director of the National Transplant Organisation, Madrid

The ONT is the technical organization in charge of organizing, planning and coordinating transplantation of organs, tissues, and bone marrow. The ONT is responsible for implementing the “Spanish Model” which led to a vast increase in the levels of organ donations in Spain. From 1990 to 2000 and again from 2004 to now Dr. Matesanz is the president of the Ibero – American Network / Council of Organ Donation and Transplantation. For 7 years he was the Chair of the European Committee of Transplantation of the Council of Europe. From 2001 – 2006 he was the President of the Spanish National Commission of Nephrology and from 2005 to 2006 Secretary of the Spanish National Commission on Nephrology. Among many other positions he has held over the years is that of adviser in the field of organ donation to the Institute of Medicine in the USA and adviser to the World Health Organisation in the global strategy of transplantation. He is the author of more than 500 articles in international journals and more than 100 chapters of books or monographs about nephrology, organ donation and transplantation and clinical management.
Professor Dr. med. Dr. phil. Eckhard Nagel  
Chief of the Surgery Centre and Transplantation Centre, Augsburg, Germany

Eckhard Nagel studied medicine at the Medical University in Hanover as well as at the University of Vermont (USA), the Dumfries Royal Infirmary (UK), the Universitaire de Grenoble (France) and the Dartmouth Medical School in New Hampshire (USA). After graduation he worked as research assistant and later as Chief Medical Doctor in the Clinic for Abdominal- and Transplantation-Surgery of the Medical University in Hanover. Additionally Dr Nagel studied Philosophy and History at the University of Hanover graduating with a PhD in 1995. In 1999 he became Professor for Medicine Management and Health Research at the University in Bayreuth. Since 2001 he is the Director of the Institute. He is also the head of the Transplantation Centre as well as Chief Medical Doctor in the area of General-, Visceral-, and Transplantation-Surgery of the Surgery Centre of the Clinic in Augsburg. He also cares for patients in his function as chairman of the board of trustees of the Rudolf-Pichlmayr-Foundation and Chief Surgeon of the Sonderkrankenanstalt Ederhof „Rehabilitation für Kinder und Jugendliche nach Organtransplantation“ in Stronach, Austria. Apart from the membership in various boards and working groups of the "Bundesaerztekammer", Dr Nagel was a Member of the Board of Trustees of the Hanns–Lilje–Foundation and since 2000 its chairman. In 2001 Eckhard Nagel was called to the National Council on Ethics and elected its vice chairman.

Håkan Hedman  
President of the Swedish Kidney Association

Mr Hedman was born 1951 and lives in Gothenburg Sweden. He was educated as a Marketing Economist and graduated in 1982. He is employed at Jotun Marine Coating a Norwegian global paint manufacturer. Mr Hedman had a kidney transplant 1985. He has been the president of Swedish Kidney Association for the last 24 years. He is also the chairman of Livet som Gåva - Gift of Life and Professor Lars-Erik Gelin Memorial foundation for transplant research.
ANNEX I: PROGRAMME

Panel 1 - Policy and institutional representatives

09:15 Welcome and opening – Dr. Miroslav Mikolášik, MEP, Rapporteur for the Directive and Andrés Perelló Rodríguez, MEP, Rapporteur for the Action Plan

09:30 The EU’s efforts to provide high quality and safe transplantation systems – Dr. Andrzej Rys, DG SANCO - Health and Consumer Protection

09:45 Message from the Spanish Presidency – Dr. Enrique Terol García, Health and Consumer Advisor-Permanent Representation of Spain to the EU

10.00 Questions and Answers

Panel 2 - Distinguished Experts and patient representative on best practices in Europe on organ donation and transplant

10:15
1. Dr. Rafael Matesanz, Director National Transplant Organisation (ONT), Madrid, Spain
2. Dr. Alessandro Nanni Costa, Director of Italian National Transplant Centre, Rome, Italy
3. Professor Dr. med. Dr. phil. Eckhard Nagel, Chief of the Surgery Centre and Transplantation Centre, Augsburg, Germany

11.00 Questions and Answers

11.20 A Patient’s story: living with an organ transplant – Håkan Hedman, Swedish Kidney Association

11.35 Discussion

12.30 Closure
ANNEX II: PRESENTATIONS
A PRACTICAL APPROACH TO QUALITY AND SAFETY IN ORGAN TRANSPLANTATION

Alessandro Nanni Costa
Italian National Transplant Centre

DONATION AND TRANSPLANTATION PROCESS

DONOR IDENTIFICATION
DEATH DIAGNOSIS
DONATION SUITABILITY ASSESSMENT
CONSENT TO DONATION
MAINTENANCE
ORGAN ALLOCATION
WAITING LIST
ORGAN AND TISSUE RECOVERY
TRANSPLANT
FOLLOW UP
SAFETY AND QUALITY: the points of contact

- Sensitize staff
- Dissemination of working procedures (manuals)
- Training
- Continuous education
- Report of adverse events, of their causes and consequences
- Identification of responsibilities
- Assign activities according to qualifications and skills

QUALITY and SAFETY CAN NEVER BE TAKEN APART

WHAT IS THE MEANING OF QUALITY?

POSSIBILITY TO VERIFY THE PROCESS DEVELOPMENT IN EACH PHASE

IDENTIFICATION OF MEASURABLE, REPRODUCIBLE, COMPARABLE INDICATORS

WHO IS SUPPOSED TO DO IT?
Competent Authority or its delegate body

FROM DONATION
TO ORGAN RECOVERY
TO ORGAN ACCEPTANCE
TO ORGAN ALLOCATION
TO TRANSPLANTED PATIENT
TO PATIENT FOLLOW UP
TRACIBILITY AND QUALITY: USERS

TRANSPANT INFORMATION SYSTEM

citizens GPs recipients CNT / MINISTRY REGIONAL CENTRE NHS UNIT Transplant centre ICU

TRACIBILITY AND QUALITY: ACTORS INVOLVED

Information and training - Observatory over transplant activities - Quality and Transparency - Structures of transplant centres - Waiting lists National Progr. - Check on allocation criteria - Guidelines

CNT/ MINISTRY

REGIONAL CENTRE

Medical suitability of the potential donor - Consent

NHS UNIT

Consent to donation

Citizens

EUROCET web site - Counter on Ministry web site

GPs

Consent to donation

Recipients

Exit from list - Urgency

Transplant centre

Waiting list - Organ retrieval - Transplant - Follow-up

ICU

Brain death diagnosis
**DONOR MANAGEMENT**

**CRITICAL STEPS IN THE SYSTEM**

- TIMING
- DECENTRALIZED ASSESSMENT
- DECENTRALIZED DIAGNOSIS

Elements that may influence the management quality!

**RECIPIENT MANAGEMENT**

(General practitioners, specialised dpts, tx centres, coordinat centres)

**CRITICAL STEPS**

- Follow-up
- Transplant
- Preparation
- Summoning
- Selection for tx
- Periodical testing
- Admission/treatment
- Valutating
- Typing
- Clinical assessment
- Indication to tx
- Diagnosis

**CONSEQUENCES**

- Dishomogenous information to patients;
- Inadequate or poor information on possible therapeutical options;
- Different criteria for screening and admission;
- Different composition and management of waiting list;
- Dishomogenous or non-transparent allocation criteria;
- Puzzlement, comparison with other experiences;
- Preclusion of choices, conditioning of health care pathway;
- Patient mobility over the national territory;
- Perception of inequalities, non-comparable waiting list satisfaction indexes;
- Risk of poor ethics and transparency in the system;
FAILURE TO IDENTIFY THE PERSON RESPONSIBLE FOR FOLLOW-UP

- Discontinuous relationship physician-patient;
- Possible “differences” in follow-up approach;
- Difficulty in operational coordination between general practitioner and specialist;

ALTERNATION OF INTERLOCUTORS

- Behavioural differences in prescriptions and patient healthcare;
- Possible duplication of physician interventions;
- Non-personalized management of follow-up;

FACTORS INFLUENCING THE PERCEIVED QUALITY

THIS IS NOT THE END... BUT THE START OF A NEW PROCESS

MANAGEMENT OF TRANSPLANTED PATIENT
(Transplant centres and/or specialized dpt of origin)

POST TRANSPLANT FOLLOW-UP

Since the year 2000 the quality of transplants in Italy is measured on a national basis, through the Italian National Information System

DATA ARE PUBLISHED ANNUALLY ON THE HEALTH MINISTRY WEBSITE
The shortage of donors has stimulated the development of strategies that might allow organ procurement from donors with infections or tumours that have disqualified them from the donation in the past.
Evaluation of acceptability or not of every organ is not absolute.

The risk profile is evaluated comparing donor risk factors, type of organ offered with the relative risks and clinical characteristics of the recipients.

The patient's consent to accept an organ from a “non-standard risk” donor must be obtained at the time of listing and again when the organ is offered (consent form).

If the patient has only a short time to live, he/she may be prepared to accept an organ with a higher risk of either failure or disease transmission, if the choice is between life and death.

However, the transplantation of materials from a high behavioural risk donor for non-life threatening conditions cannot be justified.

It is essential to screen donors and establish the presence or absence of disease transmission risk in their organs and tissues.
VIRUSES
- HSV-1
- HSV-2
- VZV (HHV-3)
- EBV (HHV-4)
- HC MV (HHV-5)
- HHV-6
- HHV-7?
- HHV-8
- HIV
- HBLV-1+2
- HBV
- HC V
- HDV
- WEST NILE VIRUS
- Rabies virus
- LC MV
- Arenavirus
- BKV?
- SARS-CoV?
- TSE?

PROTOZOA
- Toxoplasma gondii
- Trypanosoma cruzi
- Plasmodium spp.
- Echinococcus granulosus

BACTERIA
- Gram-positive
- Gram-negative
- Mycobacteria

FUNGI
- Candida spp.
- Aspergillus spp.
- Coccidioides immitis

DONOR TRANSMISSIBLE INFECTIONS

Emerging Disease

Aedes albopictus: the primary chikungunya virus vector in the current Indian Ocean outbreak.

Aedes aegypti: the primary chikungunya virus vector in Asian chikungunya outbreaks.
ITALIAN SAFETY GUIDELINES

28.12.2003
Supplemento ordinario alla GAZZETTA UFFICIALE
Serie generale - n. 397

DELIBERAZIONE 26 novembre 2003.

Accordo tra il Ministero della salute, le regioni e le province autonome di Trento e Bolzano sul documento recante:
- il manuale per l'acquisto delle sieroterapie dei donatori di organi.

LA CONFERENZA PERMANENTE PER I RAPPORTI TRA LO STATO LE REGIONI E LE PROVINCE AUTONOME DI TRENTO E BOLZANO

DEFINITION OF RISK LEVELS

GUIDELINES

1. UNACCEPTABLE RISK
2. INCREASED BUT ACCEPTABLE RISK
3. CALCULATED RISK
4. NOT ASSESSABLE RISK
5. STANDARD RISK
COMPLEXITY OF TRANSPLANT FIELD GIVES RISE TO SITUATIONS AND PROCESSES THAT CANNOT ALWAYS BE FORESEEN IN A REFERENCE GUIDE

- A 24/7 support by specialists in Infectious Disease, Pathology and Legal Medicine is available for a second opinion on organ suitability and therapeutic suggestions for either donor and recipients.
- All the centres transplanting organs from infected or neoplastic donors are asked to supply regularly follow-up data to the National Centre for Transplantation.

SECOND OPINION EXPERT GROUP

DONOR ASSESSMENT

D.M.02/08/02: Criteria and terms for organ suitability certification

DYNAMICAL PROCESS

- Before retrieval
  - Medical history
  - External examination
  - Biochemical tests
  - Serological tests
  - Tool tests
  - risk levels

- During retrieval
  - Histology
  - Biomolecular tests
  - Palpation
  - Inspection
  - confirmed or modified

- During transplant
  - Back-table surgery
  - Autopsy
  - definitive risk level

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TIMING OF NEOPLASIA IDENTIFICATION

- Pre Retrievial
- Retrieval
- After Transplant

LEGENDA:
(n. cases; % over the total)

UTILISED NEOPLASTIC DONORS
PER PHASE OF DETECTION: 2006-2008

- Before recovery
- Before transplantation
- After transplantation

LEGENDA:
(n. cases; % over the total)
### “CALCULATED RISK” EFFECTIVE DONORS AND ORGANS
#### WITH RELATED TRANSPLANTS - JAN 2003-DEC 2008

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Total = 2992

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**AND YET, SOMETHING MAY GO WRONG**

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**Una bomba nel corpo Trapianti a rischio Hiv**

Un caso per caso: un'opera tragicamente risolta da tre pazienti

*La biologa scrive ai tre pazienti: “Non ho scusati, soffro insieme a voi”*
HIV-positive organs used for transplant in Italy due to human error

E Villa, A Nanni Costa
Centro Nazionale Trapianti, Rome, Italy

Eurosurveillance weekly release: 8 March 2007

In February 2007, three patients received HIV-positive organs as a result of an error made in the documentation by an employee at the hospital in northern Italy where the organs had been taken for transplant. The person wrote “negative” instead of “positive” after reading the automatically generated print-out report of the results of laboratory analyses, including blood testing for HIV. The organ donor was a woman in her forties who died at home of a brain haemorrhage but had no clinical history of any diseases. After her death, the family had assented to organ and tissue donation not knowing that she had been HIV-positive. Three organs (two kidneys and a liver) were transplanted to three distinct recipients.

The delay in communicating this event was declared by the Italian transplant network to be a violation of the national and regional guidelines that demand the prompt alert of the entire system.
While donor evaluations may be improved, it is unlikely organ transplantation can ever be absolutely free of disease transmission.

The risk remains low as evinced by the thousands of beneficiaries of transplantation.

In the meantime, our patients will benefit from expanded reporting of donor-derived infections and basic research into the development of improved diagnostic tools.


For most people an organ transplant extends life expectancy and can dramatically improve their quality of life.

Because of the organ shortage, all available organs should be considered for transplantation as a recipient whose life is in danger may accept a risk of disease transmission.

There is a balance to be considered, the risk associated with the organ versus the consequences of not getting a transplant. However, the transplantation of an organ from a high risk donor for non-life threatening conditions cannot be justified.

It is therefore essential to screen donors and recipients in order to evaluate the risk/benefit ratio.

Safety and quality measures must be introduced in every step of the transplantation process.
Implications and Options of the European Law – A doctors perspective

Univ.-Prof. Dr. med. Dr. phil. Eckhard Nagel

Contribution to an expert hearing in the European parliament 19.11.2009

Starting Point

Organ transplantation represents fundamental progress for the individual and for the society
Changes within Society through the Development of Organ Transplantation

- Transplantation as a gold-standard
- Significant improvement of the quality of life for patients and their dependents (E. Nagel / M. Niechzial 1997)
- Reality of the Tx-medicine: 3 patients who are on the waiting list die per day in Germany

STOP Unethical
Human Organ Harvesting in China
停止在中国活体摘取人體器官的現行

Canadian Independent Investigation
Concludes CCP Harvesting Organs from Living Falun Gong Practitioners
1997-2007: 10 years transplantation-law Germany

- Existing legal security
- Unified federal waiting list
- No organ trade in Germany
- Complete transparency in the distribution of organs
- Successful quality management

Transplantation medicine in the European context

- Previous cooperation on European level: i.e. Eurotransplant and other European institutions (i.e. Scandiatransplant, France Transplant)
- 22.04.2008: Resolution by the European Parliament on organ donation and transplantation: measures on EU level [(2007/2210(INI)]
Transplantation medicine in the European context

- Next steps:
  - Proposal for a Directive from a Council working group
  - Reading in the European Parliament

Suggested measures on EU level (I)

- Increase of organ supply
  → i.e. through the strengthening of transplantation coordinators in hospitals, strengthening of live donation, EU wide cooperation
- Improvement of the access and development of efficient structures in transplantation medicine
  → i.e. Further development of organisation models, European wide data registers, introduction of a European Organ Donor Card
Suggested measures on EU level (II)

- Sensitisation of the public
  - Information, training for doctors and no-medical health practitioners and self help groups
- Guarantee of quality and security
  - i.e. EU accreditation authority, EU-wide performance indicators, avoidance of disease transmission, long term studies/evaluations
- Prevention of organ trade
  - common strategy for the fight of international organ trafficking (also for the protection of the EU)

Options and implications of the European law

- The primary authority in the development of health policy lies with the Member States (Art. 152 EGV und Art. III-278 of the EU Constitution)
- The European Community Treaty (Art. 152 (5)) and the EU Constitution (Art. III278 (7)) determine in particular the competency of the single states regarding organ donation and distribution
The tasks and goals in EU health policy are limited, including for example patient security and public health and consumer protection.

Germany has the highest security, quality, and transparency standards.

EU-wide standardisation on this level is currently unrealistic.

An increase in the organ supply should be provided through local measures (i.e. strengthening of the transplantation coordinators).

Possible Differences on a European level:
- Prerequisite for organ removal (cardiac death vs. brain death)
- Inclusion on the waiting list
- Allocation guidelines for the organ distribution
- Societal perception on organ translation

Additional administration and discussion effort could in the end lead to a reduction in the amount of donors.
A purely practical perception, focussed only on the quality and security of organ donation, perception does not capture the complex ethical and societal problems in translation medicine.

The reasons for a positive perception of organ donation within the different EU countries are extremely divergent. Perceptions depend on beliefs related to the societal context:

- Hippocratic ethics
- Christian-western values (charity)
- Moral concept of the Enlightenment (aspects of freedom)
Ethical questions and organ transplantation

- Instrumentalisation of the human body
- Anthropological significance of the brain death concept
- Distributive justice in organ allocation

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Ethical questions and organ transplantation

- Doctors responsibility in live donations
- Commercialisation of the organ donation
- Lack of organs
- Individual and societal decision-making autonomy
How can the available organs be distributed in an fair manner among the large amount of patients that are on the waiting list?

Scarceness of organs & allocation difficulties

- The principle of utilitarianism is mainly applied
- The placement is done mainly through the criteria: chances of success and priority

Equity & doctors responsibility
Moral concepts

Existential need in the utility calculus—material value of human existence

Sociopolitical challenges

- Primarily it is necessary to reduce distrust towards transplantation medicine
- The distrust lies in a unresolved contradiction:

Utilitarian-economic image of humanity  \[\rightleftharpoons\]  Principle of organ donation
Challenges for Europe

- Strengthening trust in the vision of the European Unifying process
- Dealing with differences – Acceptance of divergence i.e. anthropological dualism

The human as a material being

The human as a unity of body and soul

Thank you very much of your attention!

Eckhard Nagel
Håkan Hedman
President
Swedish Kidney Association

50 years
Experience and Perspective
of Renal Care

Håkan Hedman
My 50 years as kidney patient:

- 1960 – 61 9 months in hospital
- 1961 – 75 Regular medical check up
- 1975 – 76 Diet treatment
- 1976 Start of dialysis
- 1976 First transplantation (only 3 weeks)
- 1976 – 85 Dialysis
- 1985 Transplantation (kidney from Brussels)
World Transplant Games

Swedish Team Singapore 1989

A personal target is reached

The best time is today!
2008

I got these benefits:
• Quality of life
• Family
• Independent life
• Good health
• Less contacts with health care
• Full time work
50 years experience

Summary of 50 years perspective on Renal Care:
• Dialysis
• Transplantation
• EPO (Erythropoietin)
• Understanding of children in hospital
50 years experience

How to contribute organ donation:
• No legal barriers
• Information to general public
• Information to health care personal
• Promote living donations
• Develop routines in the health care system
• Patients organisations an important part

Thank you for your attention!
Role

Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

Policy Areas

- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents