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REPORT

Policy Department
Economic and Scientific Policy

# Organ donation and transplantation: Policy options at EU level

## Briefings dialogue and report

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Mrs. Ruth-Gaby Vermot-Mangold, Prof. Herman Nys -
**Experts invited for the Dialogue Session**

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# 1. Introduction

On 3 May 2007, the European Commission adopted a Communication on "Organ Donation and Transplantation: policy actions at EU level"[1]. Organ donation and transplantation are highly sensitive and complex issues with important ethical implications, requiring the full involvement of relevant organisations. The various aspects of these issues are approached differently in Member States according to differing cultures, laws, public administration, and organisational practices.

The European Parliament Environment, Public Health and Food Safety Committee is currently preparing a report on organ donation and transplantation (Rapporteur MEP Dr Adamou, GUE/NGL).

The present **Briefings Dialogue** has been organised to provide a forum for more background material and to clarify aspects related to the topic of Organ Donation and transplantation in the European Union.

This event will take place in the European Parliament in Brussels, on 27 November 2007 – from 15h00 to 16h30.

The Dialogue Session will focus on four key issues, presented by four different experts:

1. Transplant Risks
2. Organ Shortage and Availability
3. Organ Trafficking
4. Legal Rules and Existing Initiatives / Activities in the E.U.

The Briefings Dialogue is organised by the **Co.Meta Consulting Company** together with the European Parliament Environment, Public Health and Food Safety Committee and the EP's Policy Department A.

All information is available on:

- the webpage for external expertise for the Committee on Environment, Public Health and Food Safety: http://www.europarl.europa.eu/comparl/envi/externalexpertise/public_health_en.htm
- the website of the Co.Meta Consulting Company, in charge of organising the event: http://www.consorziocometa.it/organdonation

[1] Relevant European Commission documents are COM(2007)275 ; SEC(2007)704 ; SEC(2007)705. They can be found on the EC webpage: http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/oc_organs_en.htm

## 2. Dialogue session - Programme

# "Organ Donation and Transplantation: Policy options at EU level"

**BRIEFINGS DIALOGUE**

**European Parliament, Brussels**
**Altiero Spinelli Building, Room ASP A3G2**

**27 November 2007 --- 15h00-16h30**

**PROGRAMME**

15:00 Welcome and opening – Rapporteur MEP Dr Adamos ADAMOU and Shadow Rapporteur MEP Mrs Frieda BREPOELS

15:10 Prof. Stefano Maria GIULINI (Università di Brescia – Director of the Executive Unit of General Surgery, Italy): *Transplant risks, quality and safety of organ donation and transplantation*

15:20 Mr Mark MURPHY (CEO of the Irish Kidney Association – Member of the European Kidney Health Alliance, Ireland): *Organ shortage and availability*

15:30 Mrs. Ruth-Gaby VERMOT-MANGOLD (Member of the Council of Europe – Member of the Swiss Parliament, Switzerland): *Organ trafficking*

15:40 Prof. Herman NYS (Katholieke Universiteit Leuven – President of the Belgian federal commission of patient rights, Belgium): *Legal rules in the Member States and existing initiatives/activities*

15:50 Discussion

16:20 Concluding remarks by MEP Dr Adamos ADAMOU

Venue: European Parliament – Altiero Spinelli Building ASP A3G2
Brussels, Rue Wiertz 60 (main entrance)

## 3. Curriculum vitae of the experts

## Prof. Stefano Maria GIULINI

*(Università di Brescia – Director of the Executive Unit of General Surgery, Italy)*

Born in Rome, the 18th of March, 1944.

Graduated "cum laude" in Padova, Specialist in General Surgery and in Vascular Surgery.

Full Professor of General Surgery and Director of the School of Specialization in General Surgery of the University of Brescia.

Director of the 3rd Division of General Surgery of the University Hospital Spedali Civili di Brescia, competent in abdominal surgical oncology, vascular surgery, kidney Transplantation.

Director of the Department of General Surgery of the same institution, including five divisions of General and Emergency Surgery.

Director of the Department of Medico-Surgical Sciences of the University of Brescia.

Former component of the Ethical Committee.

Scientific Director of the "Research Centre on the surgical hepatic diseases" financed by public and private institutions.

Italian coordinator of the co-operative partnership between the University Louis Pasteur of Strasbourg and the University of Brescia.

Author of 400 scientific publications.

Component of the editorial board of scientific journals and member of the council of scientific societies and research foundations.

## Mr Mark MURPHY

*(CEO of the Irish Kidney Association – Member of the European Kidney Health Alliance, Ireland)*

Mark Murphy is the Chief Executive of the Irish Kidney Association, (IKA). He has over 25 years experience as a carer for Patient's with End Stage Renal Disease.

He is an active participant in the management of the European Kidney Health Alliance (EKHA), The European Kidney Patient Federation (Ceapir), The World & European Transplant Games Federations (WTGF & ETDSF) and former Director of the International Federation of Kidney Foundations (IFKF) whose Annual Conference will be hosted by Ceapir in Mainz, Germany in May 2008.

His National Patient Organization, the IKA recently hosted the Council of Europe's 'European Day for Organ Donation and Transplantation' in Dublin in October 2007.

## Mrs. Ruth-Gaby VERMOT-MANGOLD

*(Member of the Council of Europe – Member of the Swiss Parliament, Switzerland)*

**Personal**

Profession: Anthropologist, PhD / Member of Swiss Parliament / Member of Swiss Delegation in Council of Europe (Human and Women Rights)

**Education/Training**

Studies (PhD) of Ethnology and Sociology in Switzerland, Austria and Germany. Research in Africa, dissertation about "The Rights of Women" (Togo, West Africa). Further education and trainings in team supervision, organisational consultancy and coaching of people in management positions.

**Professional Carreer**

Project leader and evaluation of projects in West Africa, combined with ethno-sociological studies. Established and lead the information, documentation and education centre for Third World studies in Bern/CH. Teaching at various universities, focussing on gender, migration, racism. Founded her own consultancy office with a partner in 1989.

**Political Career**

***Member of Swiss Parliament since October 1995***

Political priorities: human trafficking and organ trafficking, illegal child adoption, refugees, migration, racism, gender issues, drug policy, peace and human rights policies and domestic violence etc.

***Member of the Council of Europe since October 1995***

Member of the "Committee on Migration, Refugees and Demography" as well as the "Committee on Social, Health and Family Affairs", and of the "Committee on Equal Opportunities for Women and Men". Same political priorities as in Swiss Parliament.

**Side Projects**

- Initiator and President of the association "1000 Women for the Nobel Peace Price 2005".
- President of the association "Contact Netz", a network of drug rehabilitation institutions Switzerland.
- Board member of the association "Child Protection Switzerland",
- President of the Swiss branch of the "International Society for Threatened People".

*(Bern/Switzerland, 30 November 2007 ruth-gaby.vermot@hekate.ch)*

## Prof. Herman NYS

*(Katholieke Universiteit Leuven – President of the Belgian federal commission of patient rights, Belgium)*

Herman Nys obtained a degree of master (1974) and doctor (1980) in law at the KULeuven. He specialised in medical law in European universities (Nijmegen; London). He teaches medical law in the medical and law school of the KU Leuven and has been a guest professor at the Université Catholique de Louvain and different universities in the UK and the USA. He is director of the Centre for Biomedical Ethics and Law of the KULeuven (www.cbmer.be) and he acts on a regular basis as consultant to Unesco, Council of Europe and WHO. He has been professor in international health law at the University of Maastricht from 1999 to 2005. He is the author of a standardwork on Belgian medical law that was published in Dutch (1991: second edition 2005) and French (1995). He is the editor of the *International Encyclopaedia of Medical Law*, a looseleaf review of medical law of many national states.

Prof. Nys' main research interests are genetics, biomedical research with human beings and end of life. He is past-president of the *Advisory Group on Ethics* of EuropaBio and member of the Belgian Advisory Council on Bioethics and different institutional ethics committees. He was vice president of the 14th World Congress on Medical Law in Maastricht, August 2002. From July 2003 he is the first president of the Belgian federal commission of patient rights.

# 4. Briefings

## 4.1. The risk of transmission of diseases from the donor to the recipient in organ transplantation

Prof. Stefano Maria GIULINI

*(Università di Brescia – Director of the Executive Unit of General Surgery, Italy)*

***ABSTRACT***

The risk of transmission of infectious and neoplastic diseases from the donor to the recipient in organ transplantation must be adequately considered, not to exclude any donor at risk, but to consider an eventual safe utilization of the different organs for specific compatible recipients in specific situations. To allow us to conciliate the needs deriving from the increasing organ shortage with the absolute exigency of safety, common guidelines on safety in sub-optimal donor utilization must be adopted by EU Member States. To obtain a diffuse application of these guidelines an organizational structure including a complete data base, a safety network for information and a commission of experts for real time consultation should be offered to the EU transplant centres as cultural and technical support.

***FULL BRIEFING***

**1. General introduction.**

Organ transplantation carries risks consequent to the surgical procedure, the transplanted organ rejection, the immunosuppressive therapy and the transmission of infectious or neoplastic diseases from the donor to the recipient.

The relevance of this last kind of risk in the different European Member States is largely dependent on several factors among others epidemiology, social contest, level of control on transplantation activity, technical and organizational standards.

Safety issues are often ignored when illegal commercial trade organ transplantation is practiced, due to inadequacy of screening of donors. As a consequence, outcomes of commercial transplants are reported to be suboptimal, being at high risk of malaria, fungal infections, hepatitis, and AIDS (Aquired Immunodeficiency Syndrome) for the recipient. In developed countries the transmission of diseases from the donor to the recipient is a quite rare event, thanks to the adoption of procedures apt to identify the donors at risk, not just to exclude them a priori, but to consider an eventual safe utilization of the different organs for specific compatible recipients, in specific situations.

The large imbalance between available organs and patients' needs makes it mandatory not to exclude potential donors only on the basis of a theoretical risk of disease transmission. The medico-surgical team must be able to utilize non-optimal donors, provided that a careful risk-benefit analysis has occurred, excluding unacceptable risks, and that the recipient has been adequately informed and gives his consent to the procedure.

Altruistic living donor organ transplantation offers optimal conditions for a complete, exhaustive evaluation of all the parameters indicating any risk of transmission of diseases to the recipient.

In the deceased donor the time constraints due to the required multiple activities during observation, to ascertain death, coupled with the necessity of shortening ischemia time of the retrieved organs, may have a negative impact on suitability. Despite such limitations the criteria of donor safety evaluation must be strictly respected.

To guarantee maximum safety, without loosing potential donors, guidelines and protocols, derived from large experiences and multiple revisions, elaborated by expert specialists in the field of transplantation, must be adopted.

## 2. The process of organ suitability evaluation

The process of organ suitability evaluation is a multiphase event, focused on two main aspects:

1) The definition of acceptable-unacceptable risk of transmission of infectious or neoplastic diseases;
2) The establishment of practical steps for the risk evaluation process, considering in the single case the transmittable disease, the specific conditions of the recipient with respect to the transmittable disease, (affected by the same disease, immune, infectable), the available means of prevention and treatment of the disease.

### 2.1 Risk levels are defined as follows:

#### 1. Unacceptable risk: donor excluded from donation

HIV (Human Immunodeficiency Virus) 1 or 2 positive donors, Hbs Ag (B Hepatitis Virus) and HDV (Delta Hepatitis Virus) contemporaneous positivity. Non treatable bacterial infections. Current neoplastic conditions excepted some initial carcinomas presenting low invasive attitude. All the malignant tumours at high risk of systemic spread, included some just anamnestic tumours.

#### 2. Increased but acceptable risk

In presence of transmissible disease, immediate transplantation is the only chance of survival for the patient. Tumours with transmission risk much lower than potential transplant benefit.

#### 3. Calculated risk

The presence of a specific pathogen or a serological status of the donor is compatible with recipient, who presents the same disease or serological status. Donors with bacterial disease in targeted antibiotic treatment.

#### 4. Non assessable risk

Evaluation process does not allow an appropriate risk assessment. Donor can only be used in case of emergency after informed consent of the recipient.

#### 5. Standard risk

Absence of risk factors for infections transmittable disease. Actual or anamnestic neoplastic conditions at no or minimal risk of systemic diffusion.

### 2.2 Risk evaluation process

The process of risk evaluation in the donor includes multiple operational multidisciplinary steps; in sequence: clinical history, physical examination, laboratory and instrumental diagnostic tools, histopathological tests and/or post mortem examination.

These are the general criteria on guidelines adopted by several countries: however, operative details are rather different, creating a substantial dissimilarity in the European context.

This is in contrast with the absolute need of equal high level standards qualifying the transplant activity in the whole European Union. The main objective is to ensure safe transplants performed by organs exchanged between two EU Member States and patients who migrate throughout Europe, usually from a Member State at low donor rates to another more active Member State.

A general adoption of experienced and effective guidelines could not only optimize safety and quality but also contributes to reduce organs shortage in EU increasing donation activity in those countries less virtuous in the safe utilization of suboptimal donors or organs.

In two recent Italian multi-centres surveys 10 to 20% of the utilized donors presented one or more assessed risk factors; the retrieved organs were transplanted without any morbidity for the recipient, confirming the effectiveness of the guidelines.

The reasons of the differences in organ donation and transplantation rates among European countries are multiple and complex, but, with reference to the relation between organ shortage and safety, the "2003 European Commission Overview" demonstrates that in different European countries the use of expanded criteria for donor selection is highly variable, with regard to the use of old donors and donors at risk for the transmission of diseases, with acceptance or exclusion of potential donors in the same conditions, in the different European Member States.

Following several international initiatives, and based on "2003 Organ Transplantation Survey", the European Commission promoted in 2007 an action plan for coordination of EU Member States, including specific guidelines on safety and quality.

To obtain diffuse, uniform safety standards the basis is the data collection and the analysis of donors at risk, and the results of transplantation in such conditions. The following step is the adoption of common guidelines, concerning both donor and recipient selection and, in the post-transplant phase the prevention of the transmittable disease in the recipient, when indicated, and the surveillance by adequate follow-up. In the model proposed by the Italian Centro Nazionale Trapianti CNT (National Transplantation Centre) and experienced with positive results, the safety assessment is supported by a diffuse "safety network", (where interchange of information is possible), and by a multidisciplinary "expert risk task force", to be consulted in every doubtful situation for a second opinion.

### 2.3 Good practice

For example, when an observation for potential organ donation starts in an Intensive Care Unit, a potential donor file is opened in the "safety network" connecting, the National, Interregional, Regional and Local Transplant centres and the second opinion commission of experts. The whole process of donor selection, retrieval and attribution of the retrieved organs to the recipients is monitored, guided and closed by the coordinating centre, if needed supported in the decision making process by the second opinion expert or experts. This model seems to be appropriate to favour the maximum cooperation and adhesion of the transplant centres to the European safety and quality improvement programmes, offering the best possible conditions, such as an easy access to useful or necessary information, and a 24 hours technical support and consultation service.

## 3. References

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CARDILLO M., GROSSI P., VALENTE M., GERALI P., PICCOLO G., TORELLI R., HAWORTH S. E., POLI F., SCALAMOGNA M.. Organ safety and availability: donors with potential risk factors are useful. In pubbl.

## 4.2. Organ shortage and availability

Mr Mark MURPHY

*(CEO of the Irish Kidney Association – Member of the European Kidney Health Alliance, Ireland)*

The IKA is a member of Ceapir – The European Kidney Patient Federation which in turn is a member of the European Kidney Health Alliance (EKHA). The EKHA is made up of the stakeholders in the "Kidney" community in Europe, who have all joined forces to promote and advance renal services throughout Europe for the betterment of a vast and growing number of patients. There are over 250,000 patients across Europe on kidney dialysis. This briefing intends to explain the shortage of all organs including heart, lungs and livers and of course kidneys and the difference in availability of deceased donors and subsequent organs for transplantation across Europe.

The Organizaciòn Nacional de Trasplantes (ONT) in Spain collected a series of data for the Council of Europe. The numbers are all based on per million of population and show enormous differences in the European countries' abilities to find organ donors and their subsequent use of them.

For example, from the numbers showing the 2006 deceased donations in each European country, we can see that the vast majority of donations are from heart beating donors – or brain dead donors, but recently five countries are also using non heart beating donors – particularly the Netherlands. These donors could typically be heart failure patients, not for resuscitation, and retrieval of their kidneys and liver are possible if retrieved immediately after death.

The high level in Spain is the result of investment in fully trained Donor Coordinators placed in every Intensive Care facility in Spain. The subsequent investment by Belgium and Austria in the same Donor Coordinator model has greatly increased their donor numbers. These three countries each have a presumed consent law but most probably it is the investment in Donor Coordinators that has made the difference – not the law. Presumed consent law, in practice is quite unworkable. In fact, all countries ask for consent from the deceased donor's family and respect their wishes – regardless of the law in the country.

It is a fact that there are added benefits of living donor kidney transplantation to the overall countries transplantation figures. Cyprus has a very strong Living Transplant Programme and the Spanish clearly over-rely on their deceased Donor Programme and could clearly be doing a lot more Kidney Transplantation if they developed a Living Transplant Programme, as indeed would many other countries including Ireland.

A poorly matched living kidney transplant is statistically better and will last longer than a very well-matched deceased donor kidney transplant. The time gap of a deceased kidney leaving the donors body until it is transplanted into the recipient is called the "cold ischemic time". The shorter this "cold ischemic time" the better the outcome or length of life of the transplanted organ. Up to 24 hours cold ischemic time is medically acceptable. On the other hand the living donor transplant cold ischemic time is usually about 1 hour. As a result, living donor transplant is much more successful.

Live, split-liver transplantation is possible and growing in popularity but liver transplantation strongly relies on availability of deceased donors, as in heart and lung transplantation. Clearly these three organ transplants are also directly proportional to the gross domestic product of a country and the transplant rates in emerging European countries are generally very far behind the established richer European nations.

If we pull all transplantation together, we can see that surprisingly, Austria and Belgium outrank Spain – which has by far the highest deceased donor rate in Europe. Europe's potential transplantation numbers could be double what they are and further, as many people are dying from lack of transplantation as are being saved from it. Austria can achieve 90 transplants per million of population. The rest of Europe has the potential to achieve the same. That would be over 40,000 transplant operations per year. But we are only achieving 19,000 and 11 people per day or 4,000 per year are dying on transplant waiting lists. Many more people would be put on transplant waiting lists by their doctors if more organs were available. There is some evidence of patients transferring residency between Member States to avail of shorter waiting times for transplantation in more advanced countries.

If you have 100 deceased donors you potentially could have 200 kidney transplants as a result. Seven countries achieved over 90% usage of the available donor kidneys and six countries did not achieve 85% usage. Between Spain and Italy over 1,750 available deceased donor kidneys were not used. Most certainly they were not all suitable for use. There is a necessity for cooperation between Member States to exploit the potential of organ donation and the sharing of useful organs. There are organisations across Europe cooperating and sharing organs between countries. They are called 'Organ Exchange Organisations' (OEO's). Eurotransplant is the biggest of these organisations with Austria, Belgium, Germany, Luxembourg, Netherlands, Slovenia and Croatia as participants. The International Exchange of donor organs within Eurotransplant is 20% compared to 2% in the rest of Europe. Many countries do not procure hearts, lungs or livers if they cannot make use of them themselves. They might not have the expertise to use them. These are lost opportunities for other countries to benefit. In return exchange of expertise and patients could and should be developed. What is missing is a good strong pan-European organisation. Organisation is something the EU can deliver.

If haemodialysis costs €50,000 per year per patients, transplantation costs in the first year are similar but then the patient costs drop dramatically to about €10,000 per year. There are enormous financial savings to be achieved by more kidney transplantation let alone the doubling of the patient's life expectancy and the restoration of their quality of life.

The European Union could and should use its collective power and experience in cooperation to drive all Member States into an alliance to advance this area of Medicine, held back, by a lack of deceased donors. This initiative could, and should include, the non EU States whose patients needs are equal to our own.

## 4.3. Organ trafficking: "Organ trade – or how the poor become suppliers of spare parts to rich patients!"

Dr Ruth-Gaby VERMOT-MANGOLD

*(National Councillor and Councillor of Europe, Switzerland)*

### 1. Organ trade – legal or illegal – an introduction

The impressive medical progress in transplantation medicine, modern organ preservation technology and the increasingly higher chances of survival enable a majority of transplant patients to lead a qualitatively better life today. For many patients who need a replacement organ, this progress is a bearer of great hope. A new organ usually means a new life, enables kidney patients to come off dialysis, and to escape from the hopelessness and fear that the suitable organ is not available.

But In most of the world's countries, voluntary organ donation is a problem. Many people do not even think of signing a donor card; many families do not want their loved ones' organs to be transplanted into strangers. There is a wide variety of reasons for this: often, it is ignorance, religious ideas, ethnic and cultural aspects or traditional aspects which prevent people from taking organ donation into consideration.

Today, some 135,000 people live with dialysis in Europe, and about 45,000 of them would need a new kidney. Between 20 and 40 per cent of patients are on a waiting list, quite a number of them with only little chance of receiving a kidney within a useful period of time. Misery and a belief in limitless feasibility, however, make people inventive here, too. If there are no donors close at hand, you look for them elsewhere. And the globalised market and international crime respond and organise things without delay. It is easy today to find organ donors in poor countries through the Internet – everywhere in the world; there is someone who sells organs and someone who transplants them with the necessary skill.

### 2. "Transplantation tourism"

The term "illegal organ trade" has been common currency since 1980 when rich Asians started to travel to India and other regions of South Asia to purchase organs from poor "donors". Since then, further routes have been opened: thus affluent dialysis patients – predominantly men – travel half way round the world to buy a kidney, which is often a punishable offence at home. Britons and Germans fly to India, Japanese people to the USA, North Americans to Peru, Brazil or the Philippines. In China[2], prisoners are executed, and their organs are commercialised.

Trade is organised on a professional scale. An American consultancy firm, for example, makes US clinics an offer whereby kidney patients can be placed on lists of the Arab Kidney Transplant Directory for just under 700 dollars a year. The same institution brokers kidney patients from Saudi Arabia, Qatar or the United Arab Emirates to reputable hospitals abroad. "Arab transplantation patients pay between 100,000 and 500,000 dollars for the operation," is stated on the Internet.

[2] Human Rights Watch Asia, and Laogai Research Foundation.

In other countries, too, illegal deals are practised virtually in the open; Israel being a case in point. There, the purchase of an organ is so normal that many patients do not even bother to ask their own families for an organ donation. Specific cases are known where the organ recipient paid more than 100,000 dollars to the organ trader, who then brokered an Israeli donor and a transplant in South Africa for him. Every year, up to 150 Israeli patients – this is an estimate – purchase a kidney. This plunges many into debt, or they sell their assets; others are supported by charities.

In an article in *The Lancet*[3], the Israeli Professor Friedlaender described the situation in the Kidney Transplantation Clinic of the Hadassah University Hospital in Jerusalem. He dealt with the situation of the long-term dialysis patients who without having the option of a transplant in Jerusalem, opted for a kidney purchase from non-related donors in India and in Iraq. Since Iraq was out of the question, a group of medical partners of Israeli patients got together and looked for living donors in Estonia, Bulgaria, Turkey, Georgia, Russia and Rumania. Paid donors were either recruited regionally or brought into contact with the patients from Israel.

Such kidney "transactions" are semi-officially recognised in Israel. Israeli health insurers sponsor transplants in foreign countries. Thus insurance schemes reimburse patients with the transplantation cost rate that is customary in Israel, i.e. about 32,000 dollars. The procedure is uncomplicated, for the health insurance companies do not conduct any investigations, nor do they want to discover whether the transplantation in the foreign country may even have been illegal.

**3. The case of Moldova**

The Council of Europe commissioned me to conduct a fact-finding mission in the wake of reports about organ trade from Moldova.

Moldova, one of the hotbeds of the organ trade and people trafficking, is one of the poorest countries in the East, with an average annual per capita income of 300 euros. The rural population is poor; people throng into the cities, where they are unemployed or live off rare casual labour. The possibility of selling a kidney is an economic "stroke of luck".

With the help of the Moldovan journalist Alina Radu, who has been investigating people trafficking and organ trade for many years, I met various victims of illegal organ trade. Alina Radu knows about 50 victims of organ trade personally and accompanied me to various villages to meet young "kidney donors", who live off the financial proceeds of their "donation", as it were.

The "donors" are young men aged between 18 and 28; they live in poor conditions in the countryside, where there is nothing but agriculture and casual labour. When they were offered an opportunity to travel to Turkey because they would be able to find well-paid work there, they all agreed. Nina S., the liaison woman, procured their passports, organised the trip and accompanied them part of the way. When they arrived in Turkey, they were told that there was no work but that they could sell a kidney to pay for their return journey. The process was explained to them, and they were tempted with a fee of 2,500 to 3,000 euros, which for an agricultural labourer in Moldova is tantamount to about 8 annual wages. That their "customers" paid between 80,000 and 100,000 euros – or more – for a kidney is something they only learnt later. The young men, who hardly had any possibility of refusing to donate a kidney, were taken to a house and a man called Yakub, where they were fed. In a neighbouring hospital, they were subjected to thorough examinations – always at night.

[3] *The Lancet*, Volume 359, Number 9310, 16 March 2002

The young men also had to sign a paper stating that they had donated their kidney voluntarily and without pressure. I don't know how many men, some of whom are illiterate, were really able to read and understand this text since it was written in Turkish rather than in their own language.

The young men all agreed that after the removal of a kidney, they remained in the hospital for 5 days, were then sent back home on a public coach with the agreed fee in their pockets. At home, they had to take up their heavy agricultural work again and behave as if nothing had happened – for as a rule, neither the "kidney donation" nor the fee was talked about: they were taboo. A young man, who only wanted to meet us outside the village, told us that he did not want people to know that he only had one kidney left because otherwise no woman would want him. After all, he said, he was only half a man with his one kidney.

The men had money now, although 200 euros was deducted for the trip and further expenses. One of them received an old car instead of money; the old car collapsed at the Moldovan border so that he returned home, not only short of a kidney, but also without any money. The young men then only bought those goods they had wanted for a long time: refrigerators and TV sets; one built a small house, others became increasingly addicted to alcohol, and one paid people traffickers who took his two brothers to Germany.

Back in Moldova, none of the "kidney donors" received any medical aftercare or wound treatment in the case of problems. Most of the ones we saw were exhausted. When we took the young people to the capital of Moldova, to the Head of the Transplantation Centre, to have them examined, he was shocked by their physical condition. He thought that some of them would become dialysis patients in the foreseeable future or need a kidney themselves. It goes without saying that none of them would ever be able to afford dialysis or, indeed, a new kidney.

Moldova is not the only country where kidneys can be procured illegally. The people involved are groups of brokers, qualified doctors and specialised carers. There are close connections with certain authorities, border officials and the police, who have to issue passports to organ donors, for whom safe border-crossing must be guaranteed. We can therefore be certain that many people earn more or less money from these deals. This does not come as a surprise since political, organisational and social conditions are in very bad shape in the post-Soviet Union countries, in particular. For this reason, criminal networks are able to operate unhindered.

## 4. Criminal networks

Criminal networks know how to make use of the organ shortage. They are mostly able to operate nationally and internationally without being disturbed. Opinions about these networks differ, regardless of whether they consist of internationally operating criminals or local or regional groups of people. Organ trade in Moldova, for instance, is hardly run by international crime, but rather by a regional network whose visible exponents are two women. These criminal networks profit from the many loopholes in national penal codes, from the inconsistent implementation of existing international treaties and conventions which prohibit organ trade, and from inadequate police cooperation between individual countries in connection with the fight against crime. Like the trade in drugs, arms and people, organ trade is criminal.

## 5. Facts and Figures

We must assume that existing figures are uncertain and have not really been corroborated. Current estimations show that organ trafficking remains on a relatively modest scale in Europe – but the issue is nevertheless of serious concern, since it is very likely that further progress in medical science will continue to increase the gap between supply of and demand for organs.

## 6. Situation of people who have sold her kidney

We also have to ask what it is that happens to the people who have sold their kidney. The medical journal JAMA (2001) wrote that 305 people in India who had sold kidneys were asked about their social situation six years after they had sold their kidney. All of them wanted to pay off debts with the money they received. On average, they were promised 1410 dollars for their organ, but they only received 1070 dollars. Most of them actually paid off their debts, but three quarters of them were still, or again, in debt at the time of the survey. 86 percent reported that their physical condition was worse after a kidney had been removed. A vast majority – and this also applies to young men from Moldavia – advise against kidney donation.

## 7. Traffic in organs is a Human Rights violation - The Ethic question

Traffic in organs is a violation of human dignity and a violation of human rights. An all these situations raise a number of ethical questions: Should the poor provide for the health of the rich? Should the price of alleviating poverty be human health? Should poverty compromise human dignity an health? And in term of medical ethics, should help to recipients be counterbalanced by neglect of, and harm to donors? There are proponents and vehement opponents of those who would like to open up and to regulate the market of organ donors and reward the donation of organs with money, and there are those who reject an open organ market for ethical reasons.

The British philosopher Janet Radcliff Richards is among the most "liberal". She wrote in the *The Lancet* that the poorer a potential seller, the more probable that the sale of his kidney was worth every risk. When reminded of the risk of organ trade, which is often a consequence of poverty, she said that after all, rich people were not banned from pursuing highly dangerous leisure activities, either, and that it was therefore completely incomprehensible why the poor, in particular, should be protected from themselves. However, Radcliff Richards appears to gloss over the fact that the poor do not have to be protected from themselves, but rather from the arrogant exploitation mentality of the West's "me-first" society. This group, however, is rather small, for it is clear to many experts, ethicists and organisations that people from the world's East and South, people who live in poverty, must not be reduced to being spare-part suppliers to rich patients.

At the same time, the European Platform of Organ Transplantation condemns in the beginning of this year without reservation any practice that subverts or violates a potential donor’s human rights or that involves coercion or deception.

In some countries, not only relatives, but also **"altruistic strangers"** should be able to donate organs. With regard to organs donated by living donors, it is the legislators and the transplant specialists, in particular, who are discussing a relaxation of today's rule whereby only close relatives or emotionally close friends may donate organs to each other free of charge. Thus the circle of possible donors should be extended to so-called "altruistic strangers" and to friends from an extended circle (as in Switzerland's new transplantation law).

The donations should not be paid for, but expenses such as travel, absence from work, etc., should be reimbursed; amounts of 5,000 euros are mooted. It is useful here to recall a story which was written up in *Spiegel* magazine 2 years ago: an American called Hickey from Colorado, who was 58 years of age and had taken early retirement, had to go to dialysis twice a week owing to his deficient kidney. He found an agency, "matchingdonors.com", on the Internet. During a three-month search service at 295 dollars a month, Matchingdonors found a donor, 32-year-old Robert Smitty, a truck driver from Chattanooga in Tennessee. Size, blood group, availability and the willingness to donate – everything was in order. Smitty was supposed to receive 5,000 dollars for his expenses. However, the transplant was suddenly cancelled since the senior consultant did not want to operate, being of the opinion that no one should be able to find a donor outside the waiting list and that, in addition, the brokerage firm was suspect. Hickey went to the press and received a great deal of compassion and support. Pressure on the hospital grew – finally, the operation went ahead and the transplant took place. Money was still not a debating point; whether or not money changed hands is unclear – what was clear, however, was that the life situation of Smitty, who had been addicted to drugs and was still in debt, was everything but rosy.

## 8. Recommendations of the Council of Europe

The Council of Europe demands that every effort be made to prosecute organ trade. The Council also clearly states that organ trade is not simply a problem of the countries of the East but that the recipient countries also play an essential criminal role. The Council calls upon its 47 member states to deal with the problem in political terms and to create clear-cut laws.

In order to tackle people trafficking and organ trade efficiently, it is necessary to ensure a more effective implementation of the various relevant conventions: the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin; the UN Convention against Transnational Organised Crime; and the Convention on the Rights of the Child and the Sale of Children, Child Prostitution and Child Pornography. And at last the new Convention to fight against trafficking in Human beings who is now ratified by 10 countries.

The principle to which the human body and its parts shall not, as such, give rise to financial gain is part of the legal acquis oft the COE.

In addition, member states are advised to recognise their common responsibility with a view to minimising the risk of organ trafficking by strengthening existing mechanisms of co-operation at the Council of Europe level.

"Donor countries" are advised to restrict the donation of organs and tissues from prisoners and other individuals in custody, as they are not in a position to give informed consent freely and can be subject to coercion, with the exception of donations for members of their family. Also, "donor countries" should undertake effective measures to combat trafficking in general, implement national poverty reduction strategies and create conditions for business investment.

On the other hand, the COE also suggests that "recipient countries" should maintain strict laws in regard to transplantation from unrelated living donors and should deny national medical insurance reimbursements for illegal transplants abroad. Such "recipient countries" are asked to improve donor awareness by organising national campaigns and by actively supporting the regular organisation of the European Day on Organ Donation and Transplantation.

Also, they should ensure strict control and transparency of organ registers and waiting lists and establish clear responsibilities for tracking irregularities.

The COE advises them to harmonise data and strengthen mechanisms of co-operation for the mediation and allocation of organ donation procedures, and to take steps to track down "broker" advertising (in newspapers, via agencies).

"Recipient countries" should co-operate and provide expertise to "donor" countries in connection with trafficking in human beings and organs, and they should instruct the relevant bodies of the Council of Europe.

Additionally, they are advised to develop, in co-operation with relevant organisations, a European strategy for combating trafficking in organs, and to advise and assist member states on organisational measures for putting in place an efficient transplant system to minimise the risk of organ trafficking. They should provide legal assistance in drafting specific amendments to national Criminal Codes and call on all member states to demonstrate European solidarity towards countries in Eastern Europe most affected by the vicious circle of poverty.

**9. Organ donations have primarily an ethical dimension - Conclusion**

I am of the opinion that there is no right to replacement organs even if waiting lists are long and people must, unfortunately, die. If, for whatever reasons, too few organs are donated in Western countries, if waiting lists grow and if there is no longer any hope for a prolongation of life through an organ transplant, we are never entitled to exploit other people's poverty or difficult life situation, nor to abuse them for the sake of an organ donation. No one has the right to procure organs in poor countries, in return for either good words or money. If we in the rich West need organs, we will have to launch campaigns on our own ground in order to persuade people to act responsibly and to donate their organs. Only in this way is it possible for waiting lists to be reduced, for transplants to be conducted legally, and the exploitation of misery and poverty to be stopped.

CH-Bern, November 2007 ruth-gaby.vermot@hekate.ch

## 4.4. Legal rules in the Member States and existing initiatives/activities

Prof. Herman NYS

*(Katholieke Universiteit Leuven – President of the Belgian federal commission of patient rights, Belgium)*

***ABSTRACT***

Based on a study conducted in 2006 the following recommendations are proposed with regard to the legal rules governing the removal of organs of deceased donors:

1. Member States should be free to decide whether they introduce an opting in or opting out system
2. Explicit consent or explicit refusal has to be respected
3. If one wants to involve the next of kin an opting out system is preferable
4. Quality and safety of organs are best served by an opting out system.

***FULL BRIEFING***

Based on a study conducted in 2006[4], the following recommendations are proposed with regard to the legal rules governing the removal of organs of deceased donors

***1. Member States should be free to decide whether they introduce an opting in or opting out system***

After having put the EU Member States that have enacted specific rules governing the removal of organs on the opting in/opting out scale, it has become clear that an overwhelming majority of them prefer the opting out system. Only three of them (Germany, the Netherlands and the United Kingdom) have adopted an opting in system.

Within the broad category of opting out, we have made three subdivisions according to the position of the next of kin. A very strict opting out system (also called the **French model** because this country has introduced as the first this model in 1976) does not attribute the next of kin a legal right to consent or refuse post mortem removal, although sometimes they have a right to be informed of the envisaged removal and although the practice may differ from the law in the books. A strict opting out system (also called the **Spanish model**) attributes the next of kin a right to refuse post mortem removal. A less strict opting out system gives the next of kin the right to consent to a post mortem removal. Such a system only exists in Denmark and therefore it will be called the **Danish model**.

Within the broad category of opting in, subdivisions can be made according to the position of the next of kin. A very strict opting in system leaves it entirely to the person concerned to take a decision: either explicitly consent, either explicitly refuse or not take a decision at all. A "prototype" opting in system does not leave room for involvement of the next of kin. Such a prototype does not exist in practice. The German system is the most in conformity with this prototype: when the person concerned has not taken a decision, the next of kin may consent to post mortem removal but only according to the so called presumed will of the deceased. In the Netherlands and the United Kingdom the next of kin may consent if the deceased has not taken a decision. This system comes therefore very close to the Danish model

[4] Full study, see https://www.kuleuven.be/cbmer/page.php?LAN=N&ID=392&FILE=subject&PAGE=1

### *2. Explicit consent or explicit refusal has to be respected*

***2.1***. The first rule of any regulation of post mortem removal, whether opting in or opting out, is to respect without any reservation the explicit consent or explicit refusal of the person concerned. Without any exception, all laws in all member states provide that no removal may take place when the person concerned has explicitly refused it. However, respect for the explicit consent is not guaranteed in every country. To prevent this, the law may explicitly provide that the next of kin cannot veto or overrule the explicit consent of the person concerned. This is already the case in Belgium, Denmark, Estonia and Finland.

***2.2.*** Explicit consent and explicit refusal are only legally valid if the person concerned has taken a well informed decision. The rule is indisputable. The question is: how informed? Explicit consent and explicit refusal of organ removal are so called advance decisions. They differ from actual decisions. When an advance decision to consent or refuse post mortem removal is taken, there is no specific counterparty that is legally obliged to give information and to answer questions at the moment this decision is made. To prevent uninformed decisions society as a whole (public authorities but also private initiative) has an obligation to create a situation that resembles as much as possible to the situation where a patient takes an actual. Under the Dutch and the Italian law people are explicitly asked to take a decision with respect to post mortem removal of organs. This creates the opportunity to inform people in a detailed and unambiguous way.

***2.3.*** Another possibility to prevent uninformed decisions is that the person concerned authorizes someone else to take as his legal representative the decision after his death. This possibility is only provided for in Denmark, Germany, the Netherlands and the United Kingdom. It is probably no coincidence that it are the countries with an opting in system and the country with the less strict opting out system that have up to now made provision for a legal representative to take a decision on behalf of the person concerned. It mirrors their attachment to the right to self determination. However, we recommend that countries with an opting out system also introduce this possibility in their law.

### *3. If one wants to involve the next of kin an opting out system is preferable*

Both the opting out and the opting in systems struggle with the crucial question how to deal with the very frequent situation that no decision has been made at all by the deceased. Both systems have it difficult to find an equal balance between two competing requirements. The first requirement is to show respect for the next of kin by not placing the burden of taking a difficult decision immediately after the death of a beloved one. However, respect for the next of kin also implies not to exclude them of the decision making process, which is the second requirement. An opting out system is better equipped to find this balance than an opting in system: the more a decision of the next of kin risks to run counter the will of the deceased the more difficulties they will face by taking this decision so that the first requirement is not met. This risk is quite higher in an opting in than in an opting out system. Although a decision not to give explicit consent in an opting in system does not necessarily mean a refusal of removal, one thing is sure: it can never be interpreted as consent to removal. This makes it very difficult for the next of kin to consent to removal because they may rightly fear to take a decision that runs counter the will of the deceased. In an opting out system however, a decision not to refuse removal can be explained either as a refusal or as consent because the will of the deceased is not known at all. This makes it less burdensome for the next of kin to consent to removal. And this may declare (next to other factors influencing the availability of organs) why opting out systems are likely to result in higher supply of post mortem organs than opting in systems.

### *4. Quality and safety of organs best served by an opting out system*

Although it is up to the member states to decide on the legal rules that govern post mortem removal of organs, the relative success of the opting out system in the European Union, both in terms of countries that have adopted it as in the higher supply of organs are a strong argument for the EU authorities to promote an opting out system. According to article 152 (4) of the Treaty of the European Community the Council (…) shall contribute to the achievement of the objectives referred to in this article through adopting (…) measures setting high standards of quality and safety of organs and substances of human origin".

A shortage of organs creates a situation that endangers the quality and safety of organs because people will be tempted to pay for organs, to accept any available organ, to organize organ trafficking and black markets that are difficult to control and so on. The more organs that can be retrieved post mortem in a way that respects the explicit will of the deceased and that involves the next of kin in the least burdensome way, the less people will be tempted to turn to such practices. In other words: as an opting out system is a measure that guarantees more than other systems the availability of organs is has to be promoted by the European authorities to guarantee high standards of quality and safety of organs of human origin.

# 5. Proceedings of the dialogue session: summary of the findings and the debate

(Prepared by Co.Meta Consulting Company)

## 5.1. Opening of the dialogue session

**MEP Mr. Adamos Adamou (CY, GUE-NGL)** - Rapporteur on organ donation and transplantation for the Committee of the Environment, Public Health and Food Safety - introduces the Dialogue session:

**Premise:**

The European Commission (EC) is fully aware of the importance of the issue of organ donation and transplantation. On 3 May 2007, the EC adopted a Communication on "***Organ Donation and Transplantation: policy actions at EU level"***, treating these sensitive and complex issues, their ethical dimension and the necessity for full participation of the Member States (MS) for their advancement.

The Commission conducted a survey in 2003 on legal requirements related to organ transplantation. The survey showed great discrepancies in quality and safety requirements within and between MS. Various aspects seemed to be approached differently in MS according to different cultures, laws, public administrations and organizations, practices, etc.

The dialogue session was organized to present the studies and briefings made by experts in the field and provide a forum for more background material to clarify aspects on organ donation and transplantation.

Four major issues were to be discussed by the invited experts:

1. Transplant risks
2. Organ shortage and availability
3. Organ trafficking
4. Legal rules in the EU and existing activities

The Commission will present a Legislative and Health Programme for 2008, focusing on patient safety and healthcare quality.

The discrepancies in rates of organ donation throughout the EU are explained by religious, cultural, and ethical differences. Further, it appears that some organizational systems work better than others. We need to study the differences and imitate the functional models and when possible, export best practices.

## 5.2. Expert panel

### a. Transplant risks

*(**Prof. Stefano Maria Giulini**, Università di Brescia Italy, Director of Executive Unit of General Surgery in Italy)*

The risk of transmission of infectious and neoplastic diseases from the donor to the recipient in organ transplantation must be adequately considered, not to exclude at-risk donors, but to assure the safe utilization of different organs for specific compatible recipients in specific situations. Common guidelines on safety in sub-optimal donor utilization must be adopted by EU Member States in order to conciliate the current trend of decreasing organ availability and the prime prerequisite of safety for the recipient.

Diffuse application of these guidelines is fundamental and requires an efficient organisational structure including a complete database, a safety network for information, and a commission of experts for real-time consultation. These elements should be offered to the EU transplantation centres in the form of cultural and technical support.

**b. Organ shortage and availability**

*(**Mr. Mark Murphy,** CEO of the Irish Kidney Patient Organization (IKA), member of The European Kidney Patient Federation (Ceapir), itself a member of the European Kidney Health Alliance)*

Mr Murphy's presentation shows the different activity levels for Deceased and Living Organ Donation across Europe and the subsequent organ transplant activity in Europe per country.

With the use of numerous statistics collected by the Organizaciòn Nacional de Trasplantes (ONT, Spain) for the Council of Europe, he illustrates the following:

1. There is a heavy dependence on deceased donors. Spain, Belgium and Austria have invested in this area to good result, but these and other countries should invest in living donor programs
2. Presumed consent is never workable and requires next-of-kin approval which lengthens cold ischemic time, proportionally reducing the effectiveness of organs donated
3. Europe's potential transplantation numbers could be double the current level
4. Not only would lives be saved with better coordination of organ donation, but MS would experience healthcare savings, as organ transplant is less expensive than the care for ill patients waiting for donated organs
5. The experience of Eurotransplant (active in seven EU countries) shows that increased MS coordination and organisation would improve organ availability and transplantation success.

**c. Organ trafficking**

*(**Ms. Ruth-Gaby Vermot-Mangold**, member of the Council of Europe and member of the Swiss Parliament)*

After a brief introduction where she explains the importance of the issue, Ms. Vermot-Mangold illustrates the phenomenon of "Transplantation Tourism" and in particular, she analyses the case of Moldavia through a series of facts, figures and a case study showing the situation of people who have sold their kidneys. She raises the ethical question about organ trafficking as a violation of human rights and points out the recommendations of the Council of Europe.

Her conclusion is that people should never be allowed to exploit other people's poverty or life situation for the sake of an organ donation; even as waiting lists grow and even when there are patients who risk death unless an organ is immediately available. No one has the right to procure organs in poor countries, in return for promises or money. If we in the rich West need organs, we must launch campaigns on our own ground in order to persuade people to act responsibly and to commit to organ donation. This is the only correct action toward reducing waiting lists, guaranteeing legal organ transplantation and stopping the exploitation of misery and poverty for the purpose of procuring badly needed organs.

**d. Legal Rules and existing initiatives/activities in the EU**

***(Prof. Herman Nys**, Director of the Centre of biomedical ethics and law; K.U.Leuven)*

Before introducing the fourth expert, Shadow Rapporteur **MEP Mrs. Frieda Brepoels (BE, EPP-ED)** stressed the purpose of the Dialogue Session and its importance. The goal of the meeting was to safely increase the number of donors in the EU. Mrs Brepoels talked about the comparative study on the legal rules on post mortem removal of organs in the EU Member States that was conducted by Prof. Herman Nys. The study showed three crucial items:

1. A need for closer collaboration between MS and an exchange of best practices;
2. The importance of public awareness by education and training of health professionals;
3. Efficient systems, similar to Eurotransplant, Scandiatransplant and the European Transplantation Network, need to be set up, supported, and developed.

Based on his 2006 study, Prof. Nys makes the following recommendations with regard to the legal rules governing the removal of organs of deceased donors:

1. Member States should be free to decide whether they introduce an "opt-in" or "opt-out" system of consent;
2. explicit consent or explicit refusal of the donor must be respected;
3. if a given system includes involving next-of-kin, an "opt-out" system is preferable; and
4. quality and safety of organs are best served by an "opt-out" system.

## 5.3. Debate

**MEP Mr. Guido Podestà (IT, EPP)** asked Dr. Giulini to clarify certain issues:

- What could cause possible errors in the evaluation of the person at risk despite the adoption of guidelines?
- What would happen when you cannot pinpoint threats of communicable diseases?
- How does the coordination of the transplantation centres with the safety networks and the Second Opinion Commission work in practice?

  Giulini answered that there are some limits in the tests so in some cases the guidelines may not apply and as such some problems in the donors may be missed, but accurate studies (ie. DNA) can be effective much earlier. In some cases, 15 days after infection, the tests can already result positive. However, these tests are not used and adopted everywhere.

  Further human errors can occur in reading the tests, transmitting test results, and so forth, so we need to adopt very precise steps in the testing phase and in the transmission of results in order to minimise the possibility of human errors.

  Regarding the second question, transplantation is a very complicated operation so complications can arise, in the post-operative phase. But these problems are manageable. There are, however, particular issues like emotional problems, ethical questions, etc. which cannot always be prevented. The issues to be faced must be clear and the patient and family must be informed immediately about any risks involved.

  Infected organs do not imply infection in the patient receiving the transplant. Often this can be prevented and often it can be treated after the transplant.

Finally a safety network is necessary. It is important to have qualified experts on call who can be consulted in real-time. There is a connection 24/7 between the transplant centre and the experts. In this way difficult decisions can be made without wasting time that might result in losing donors.

**MEP Ms. Margrete Auken (DK, Greens)** pointed out that people are not dying because of shortage of organs but because they are ill. That aspect, according to her, must be clear. There will never be enough organs. It should not be considered a "right" to have an organ; it should be considered as a "gift" from the dying or deceased person.

There should be more communication with patients, at such a critical time, nobody knows what is going on; patients must be provided with adequate counselling and expert instruction. Behind each donation there is a tragedy; a broken family that must be respected as well as the recipient patient. How can we achieve more organ donation while respecting human tragedies?

Prof. Nys answered by agreeing on the first point, which is that it should be considered as a gift, but there should also be a system that deals with it in practical ways.

He disagreed however about organ receipt not being a right, when and if an appropriate and safe organ is available. In this case, Prof. Nys feels the patient does indeed have the right to receive it.

**Mr. Alireza Bagheri**[5] commented on Ms. Vermot-Mangold's presentation. Mrs Vermot-Mangold had pointed out that coordination should be made between MS, while Mr. Bagheri indicates a need for *global* coordination. Mr. Bagheri asked about Ms. Vermot-Mangold's recommendations. He also asked how EU countries might collaborate with Asian countries.

Ms. Vermot-Mangold replied by confirming the importance of the problem of organ trafficking, reiterating that it is tantamount to the trafficking of human beings. She recommended that this issue should be put on the agenda, and be discussed at all levels - the broad public, healthcare, public and private sector - so that this crime be dealt with. Interpol needs to work on that internationally, and give the topic a higher priority.

**Mr. Michael Bos**[6] pointed out that legislation in most MS forbids trafficking, but in several cases, in practice, insurance companies reimburse patients who go abroad to get cured in countries that have no policy against organ trafficking. Oftentimes, insurance companies pay without asking about the origin of the transplanted organ (ie: in Israel). He asked if the panel were aware of this issue and what might be to avoid this practice.

Ms. Vermot-Mangold confirmed this problem and said that Israel decided that insurance companies shall no longer liquidate these cases. She thinks that other countries should follow this example. Political pressure needs to be applied.

**Mr. Yves Vanrenterghem**[7] says that this issue can only be solved if we work together in a global perspective. He offers the example of the Chinese minister of health, who has had contacts with the International Transplantation Society and has organized a meeting. On July 1st 2007, China passed legislation prohibiting the use of organs from executed prisoners being transplanted into foreign patients. In other words, international collaboration can have real results!

European transplantation initiatives should include activities in the in global sphere, in order to foster more effective cooperation.

[5] Vice-President of the Asian Bioethics Association and Coordinator of Asian Transport on Organ Trafficking
[6] Member of Eurotransplant and Health Council of the Netherlands
[7] Chairman of the department of Nephrology at the Leuven University, European representative in the board in the International Transplantation Society, and vice- chairman of the global Alliance for transplantation

Another person in the audience reminds the panel that legislation is always slower than progress in medicine. Only the most sensitive issues, such as death, authorization and consent, allocation, and organ trafficking, should be dealt with. The new directives should be clear and limited to the "principles", neither too long nor too complicated in order to avoid confusing the issues. Some points should be required and obligatory in the directives. For example, living donors should be followed after the donation to keep track of their situations, post-op complications, and so on.

**MEP Ms. Kathy Sinnott (IR, Ind/Dem)**, Shadow Rapporteur, remarks that we can search the world for organs, and miss the fact that we are ineffective in our own backyard. She points out, for example, that potential donors are often overlooked simply because no one asks them, on the assumption that someone already has. We must not miss opportunities!

Moreover, if it *is* possible to purchase organs in Europe, people will do it. Organ trafficking IS human trafficking so we need more traceability. We need to be able to trace the organ back to its source, its donor, to prevent illicit practices and to assure organ safety and health.

Further, there are specific issues related to organ donation that must be discussed: for example, people are willing to accept organs from donors affected by Down syndrome but Down syndrome patients are not placed on priority lists to receive organs. This double standard is not right.

**Mr. Adamos Adamou** closed the event by recalling the goal of the Dialogue Session: in Europe we should aim at creating an active network of coordination among the MS. Mr Adamou also reminded experts, MEP's and guests that he will prepare an important document for the legislation and on an aside in answer Ms. Sinnott, he commented that potential living donors are usually interviewed and actual donors are always checked and traceable.

# 6. Annex: Presentations dialogue session

# THE RISK OF DISEASE TRANSMISSION FROM THE DONOR TO THE RECIPIENT IN ORGAN TRANSPLANTATION

**By Prof. Stefano Maria GIULINI**

**EUROPEAN PARLIAMENT WORKSHOP,**

**Brussels, 27 November 2007**

1


2

**Illegal commercial organ transplantation**

**Deceased donor organ transplantation**

**Altruistic living donor organ transplantation**

3

## AIM OF THE GUIDELINES ON SAFETY

1) **definition of acceptable-unacceptable risk of transmission of infectious or neoplastic disease from the donor to the recipient**

2) **establishment of practical operative modalities by steps for the risk evaluation process**

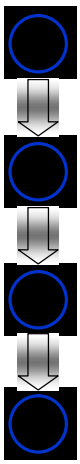
4

## GUIDELINES / 1 *Definition of risk levels*

| | | |
|---|---|---|
| 1) | **UNACCEPTABLE** | HIV 1 or 2<br>HbsAg and HDV coinfection<br>Non treatable bacterial infections<br>Malignant tumor at risk of systemic diffusion |
| 2) | **INCREASED BUT ACCEPTABLE** | Immediate transplantation is the only chance of survival<br>Risk much lower than potential transplant benefit |
| 3) | **CALCULATED** | Disease of the donor compatible with the conditions of the recipient (same disease or immune) or treatable in the recipient |
| 4) | **NON ASSESSABLE** | Donor can be used only in case of emergency |
| 5) | **STANDARD** | Absence of risk factors<br>Neoplastic conditions at no or minimal risk of diffusion |

5

## GUIDELINES / 2 *Operative modalities for the risk evaluation process*



**Clinical history**

**Physical examination**

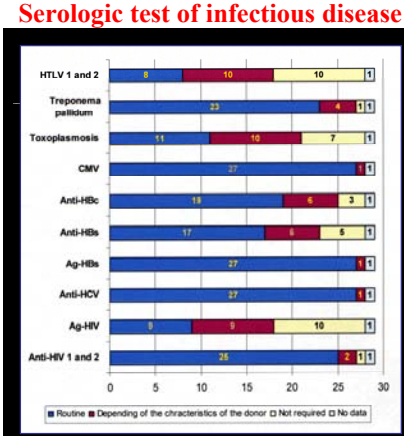
**Laboratory and instrumental diagnostic tools**

**Histopatological tests and/or post mortem examination**

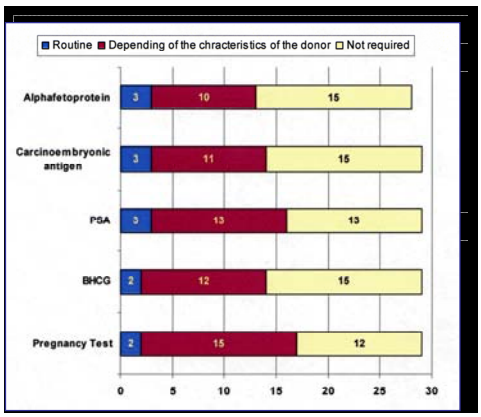
6

# DIFFERENCES AMONG EUROPEAN COUNTRIES

**Serologic test of infectious disease**




**Tumours markers**




"Human organ transplantation in Europe: an overview" – *European Commission 2003* 7

# COMMON SAFETY QUALITY STANDARDS AND GUIDELINES

**to**
- **improve safety-quality in the single EU Member States**
- **guarantee safety-quality in the** *organs* / *patients* **interchange between EU M.S.**
- **increase European donors pool**

**by**
- **accurate selection**
- **safe utilization**

→ **at risk – suboptimal donors**

8

## RESULTS OF GUIDELINES APPLICATION

from *ITALIAN NATIONAL TRANSPLANT CENTRE (2003 and 2007)*

**Increased utilization of donors at risk**

**914/4326 (~ 20%)** utilized donors were at risk
*186 tumours*
*728 infections*

**with**

**Maximum safety guaranted**

No case of donor-recipient disease transmission

9

## EUROPEAN COMMISSION - 2007

**OBJECTIVES**

- **action plan for coordination of EU Member States**
- **redaction, diffusion and application of guidelines**

10

## STRATEGY FOR INCREASING SAFETY AND QUALITY IN ORGAN TRANSPLANT ACTIVITY

- **database on safety, quality and volume of transplant activity**

- **redaction and diffusion of common guidelines**

- **support to transplant centres for application by**
  - *"safety network" for information and guidance*
  - *experts task force for a "second opinion"*

11

# *THANK YOU*

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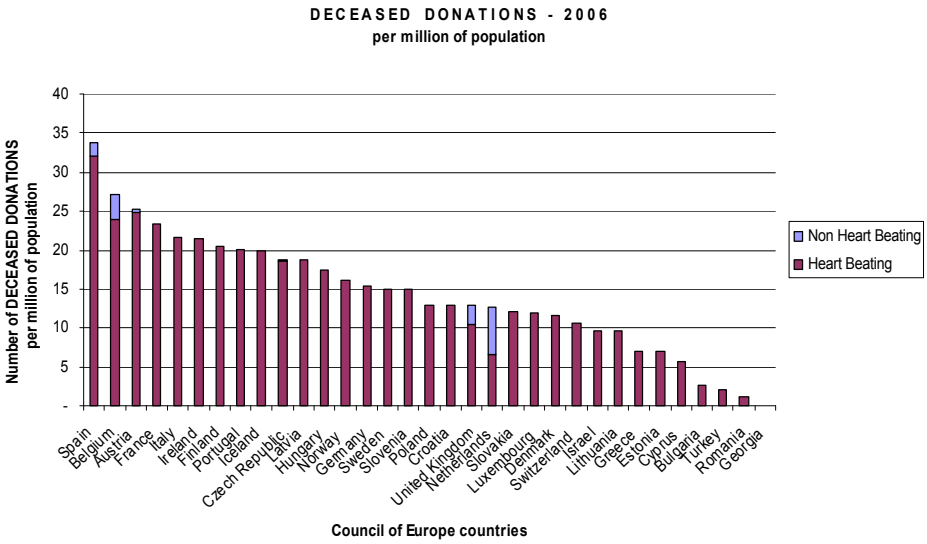
# Organ Donation Briefings Dialogue

European Parliament, Brussels

Tuesday 27th November 2007

## Organ Shortage and Availability
## Mark Murphy


DECEASED DONATIONS - 2006
per million of population
Number of DECEASED DONATIONS per million of population
40
35
30
25
20
15
10
5
-
Non Heart Beating
Heart Beating
Spain
Belgium
Austria
France
Italy
Ireland
Finland
Portugal
Iceland
Czech Republic
Latvia
Hungary
Norway
Germany
Sweden
Slovenia
Poland
Croatia
United Kingdom
Netherlands
Slovakia
Luxembourg
Denmark
Switzerland
Israel
Lithuania
Greece
Estonia
Cyprus
Bulgaria
Turkey
Romania
Georgia
Council of Europe countries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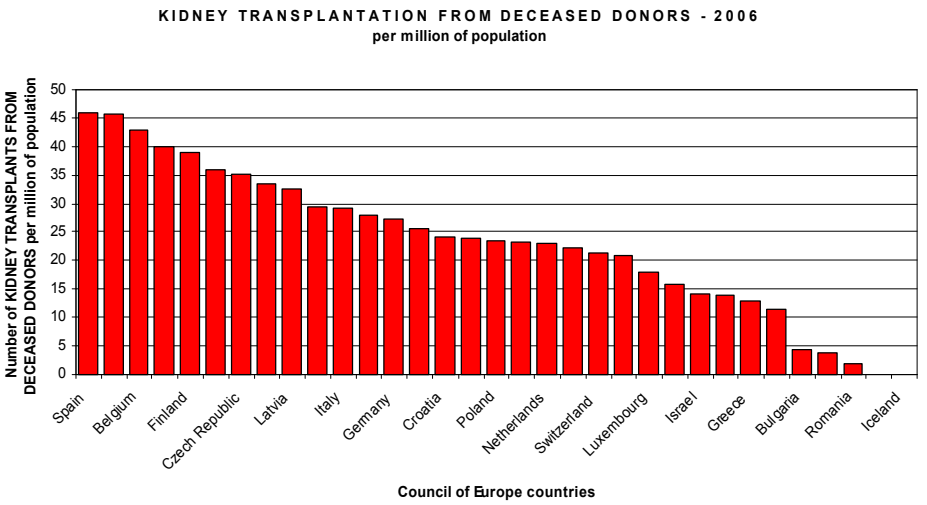
KIDNEY TRANSPLANTATION FROM DECEASED DONORS - 2006
per million of population
Number of KIDNEY TRANSPLANTS FROM DECEASED DONORS per million of population
50
45
40
35
30
25
20
15
10
5
0
Spain
Belgium
Finland
Czech Republic
Latvia
Italy
Germany
Croatia
Poland
Netherlands
Switzerland
Luxembourg
Israel
Greece
Bulgaria
Romania
Iceland
Council of Europe countries


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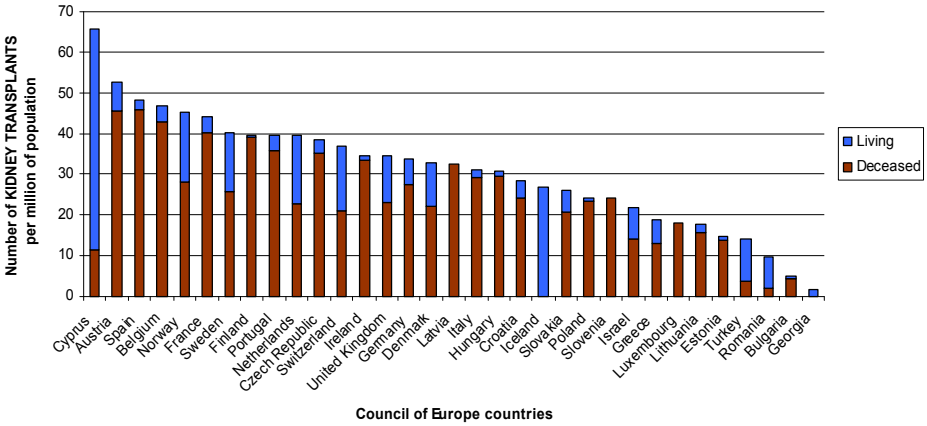
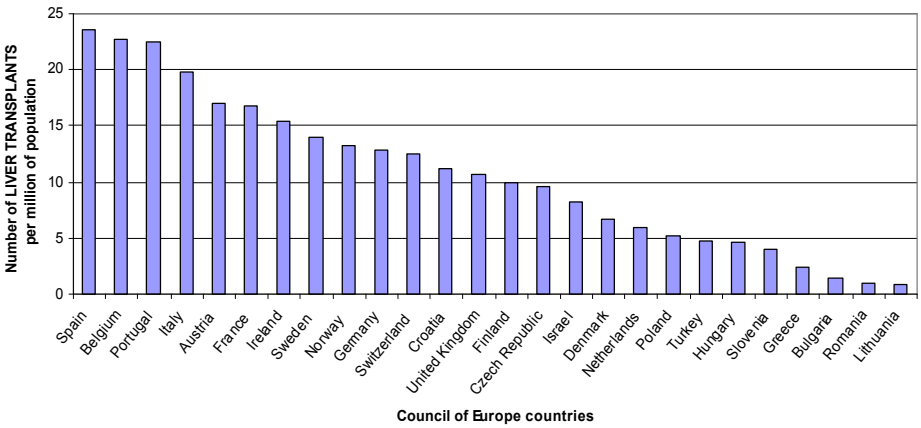
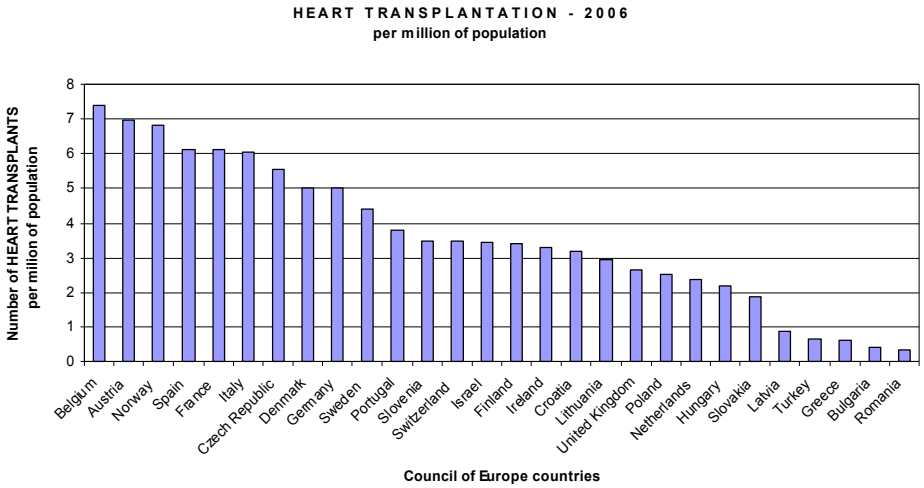
**KIDNEY TRANSPLANTATION - 2006**
**per million of population**




**LIVER TRANSPLANTATION - 2006**
**per million of population**




HEART TRANSPLANTATION - 2006
per million of population
Number of HEART TRANSPLANTS per million of population
0
1
2
3
4
5
6
7
8
Belgium
Austria
Norway
Spain
France
Italy
Czech Republic
Denmark
Germany
Sweden
Portugal
Slovenia
Switzerland
Israel
Finland
Ireland
Croatia
Lithuania
United Kingdom
Poland
Netherlands
Hungary
Slovakia
Latvia
Turkey
Greece
Bulgaria
Romania
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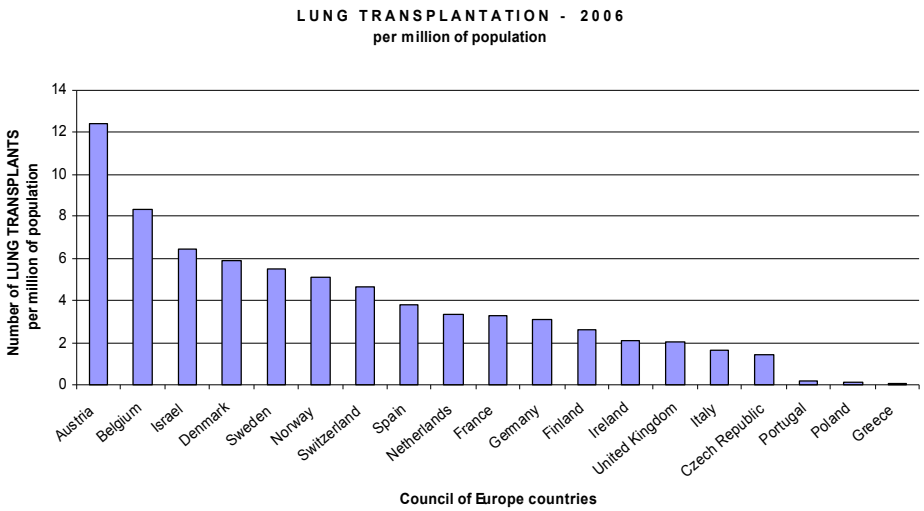
LUNG TRANSPLANTATION - 2006
per million of population
Number of LUNG TRANSPLANTS per million of population
0
2
4
6
8
10
12
14
Austria
Belgium
Israel
Denmark
Sweden
Norway
Switzerland
Spain
Netherlands
France
Germany
Finland
Ireland
United Kingdom
Italy
Czech Republic
Portugal
Poland
Greece
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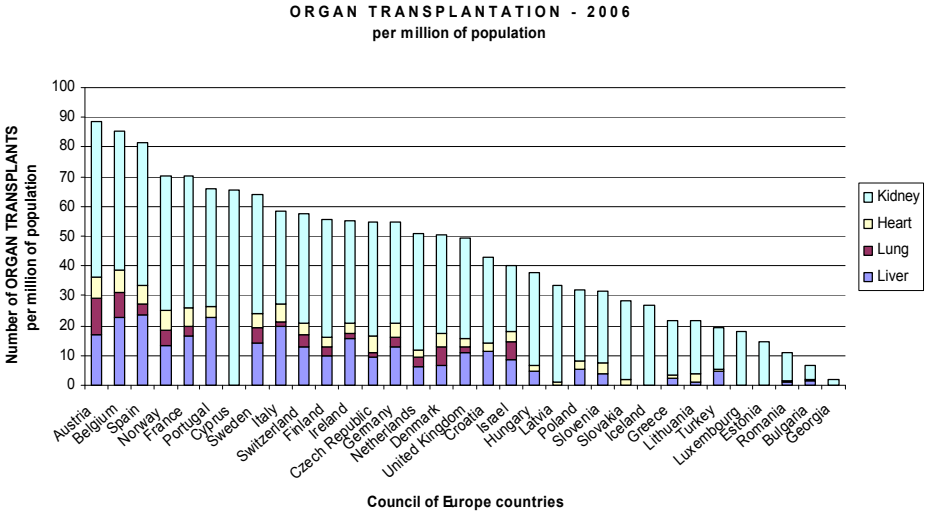


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## Potential Deceased Donor Kidney Usage Rates 2006

| | Country | Deceased Donors | Potential Kidneys (Deceased Donors x 2) | Deceased Kidney Transplants | Percentage of potential Deceased Kidneys Used |
|---|---|---|---|---|---|
| 1 | Switzerland | 80 | 160 | 159 | 99.4 |
| 2 | Denmark | 62 | 124 | 120 | 96.8 |
| 3 | Finland | 109 | 218 | 207 | 95.0 |
| 4 | Croatia | 57 | 114 | 106 | 93.0 |
| 5 | Greece | 79 | 158 | 144 | 91.1 |
| 6 | Poland | 496 | 992 | 899 | 90.6 |
| 7 | Austria | 207 | 414 | 374 | 90.3 |
| 8 | Netherlands | 211 | 422 | 378 | 89.6 |
| 9 | United Kingdom | 779 | 1558 | 1396 | 89.6 |
| 10 | Germany | 1259 | 2518 | 2254 | 89.5 |
| 11 | Portugal | 201 | 402 | 358 | 89.1 |
| 12 | Latvia | 43 | 86 | 75 | 87.2 |
| 13 | Norway | 76 | 152 | 132 | 86.8 |
| 14 | France | 1443 | 2886 | 2484 | 86.1 |
| 15 | Slovakia | 64 | 128 | 110 | 85.9 |
| 16 | Sweden | 137 | 274 | 234 | 85.4 |
| 17 | Hungary | 177 | 354 | 296 | 83.6 |
| 18 | Slovenia | 30 | 60 | 48 | 80.0 |
| 19 | Belgium | 282 | 564 | 445 | 78.9 |
| 20 | Ireland | 91 | 182 | 142 | 78.0 |
| 21 | Spain | 1509 | 3018 | 2055 | 68.1 |
| 22 | Italy | 1234 | 2468 | 1665 | 67.5 |

# EUROTRANSPLANT


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The union of member states could and should use its collective power and experience in cooperation to drive all European states into an alliance to advance this area of Medicine, held back, by a lack of deceased donors. This, initiative could and should include the non EU states whose patients' needs are equal to our own.

Thank You,

Mark Murphy.

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# ORGAN TRAFFICKING

Dr. Ruth-Gaby Vermot-Mangold
Member of Swiss Parliament an
Member of the Council of Europe
Bern, Switzerland

## THE HISTORY

*Of the Hope to Escape Poverty*
or
*Promised... Lied to... Exploited...*

The Young Men of Moldova Who Sell Their Kidneys.

## WHAT ARE THE CAUSES OF ORGAN TRAFFICKING?

- Poverty and hopelessness
- The desire to have work and make a living
- Corruption and unscrupulousness of criminels
- Globalisation of the economy and exploitation of human beings
- People in the East become the spare parts inventory for the sick in the West

## WHAT IS THE CURRENT DEGREE OF ORGAN TRAFFICKING?

- „Transplantation Tourisme“:
- Criminal networks
- Facts and figures about organ trafficking
- The situation of „donors“ a few years later

## ORGAN TRAFFICKING IS A VIOLATION OF DIGNITY AND OF HUMAN RIGHTS

- Should poor people provide for the health of the rich?
- Should the price of alleviating poverty be human health?
- Should poverty compromise human dignity an health?

## LEGISLATION

- Transplantation laws: what do they prohibit, what do they allow?
- Where are regulations necessary?

# RECOMMENDATIONS OF THE COUNCIL OF EUROPE

- Prosecute organ traffic
- Organ trafficking is a common responsability of all 47 member states
- Implement the various relevant conventions of the COE
- The human body and ist parts shall not give rise to financial gain
- Implement nationale and international poverty reduction strategies
- National campaigns
- Maintain strict laws and strict control and transparency in relation donors and recipients of organs
-

# CONCLUSION

- There is no right to replacement organs even if the waiting lists ar long and people have no chance to survive. We are never entitled to exploit other people‘s poverty or difficult life situation, nor to abuse them for the sake of an organ donation.

# LEGAL RULES IN THE MEMBER STATES AND EXISTING INITIATIVES/ACTIVITIES

Herman NYS (Leuven)

## Recommendations/ Points for discussion

- Let Member States free to decide on opting in/opting out

In practice : overwhelming majority has a (very) strict or less strict system depending on the position of the next of kin

- Explicit consent or explicit refusal has to be respected
- Guarantee informed consent and refusal by creating a situation that resembles as much as possible actual decisions
- Reinforce the role of a legal representative

- An opting out system is preferable to involve next of kin
- Quality and safety of organs are best served by an opting out system