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Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs

Joint Council of Europe/ United Nations Study

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The Study was prepared jointly by the legal expert appointed by the Council of Europe: Carmen Prior, Public Prosecutor (Austria), and the scientific experts appointed by the United Nations: Arthur Caplan, Chair of the Department of Medical Ethics and Director of the Center for Bioethics at the University of Pennsylvania in Philadelphia (United States of America), and Rafael Matesanz and Beatriz Domínguez-Gil of the National Transplant Organisation (Spain). Mr Matesanz and Ms Domínguez-Gil are both representatives on the European Committee on Organ Transplantation (CD-P-TO).

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Foreword

by the Deputy Secretary General of the Council of Europe and the Assistant Secretary-General and Special Adviser on Gender Issues of the United Nations

Trafficking in human beings is a real and growing problem all over the world. Human beings are bought and sold as a commodity. The criminals responsible for these massive violations of human rights and the rule of law are buying and selling human beings for different reasons, but the trafficking for the purpose of the removal of organs is clearly one of its most abhorrent forms. In spite of that, this form of trafficking has been relatively unknown and insufficiently researched.

The Council of Europe Convention on Action against Trafficking in Human Beings is an effective new instrument to fight human trafficking in all its forms, including for the purpose of the removal of organs. Following its entry into force in 2008 the Deputy Secretary General of the Council of Europe took the initiative to explore the Convention's specific application to this form of trafficking and the protection afforded to its victims. It quickly became apparent that the phenomenon would have to be examined in the context of the wider problem of trafficking in organs, tissues and cells. In 1997, the Council of Europe Convention on Human Rights and Biomedicine laid down the principle that it is not permissible for the human body or its parts as such to give rise to financial gain. Its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin prohibits trafficking in organs and tissues. Together with the Council of Europe activities to increase the availability of organs, tissues and cells for transplantation purposes, this multi-sectoral approach placed the Council of Europe in a very strong position to contribute to combating trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs.

The Assistant Secretary-General of the United Nations and Special Adviser on Gender Issues and Advancement of Women was concerned that organ trafficking and trafficking in human beings for the purpose of organ removal, long considered to be myths, seem to be realities all over the world. These phenomena exist for many reasons, but particularly because of extreme poverty and discrimination, including gender discrimination. In general, victims of trafficking in human beings tend to be women and children who know far too little about their rights or how to appropriately assert them. It is important to look into the existence of a gender aspect with regard to trafficking in human beings for the purpose of organ removal in particular, as well as with regard to live donators implicated in trafficking in organs, tissues and cells.

The Deputy Secretary General of the Council of Europe and the Assistant Secretary-General of the United Nations and Special Adviser on Gender Issues and Advancement of Women decided to join their efforts and agreed that the study should be prepared jointly in the framework of co-operation. As well as considering both the medical and legal aspects, it was agreed also to look at ethical problems and organisational and other measures, with a view to providing an overview of the current legal and factual situation, including from a gender aspect, examining existing measures to combat both forms of crime and exploring further avenues to fight them.

Our intention is to use the conclusions and recommendations made by the authors in this study as food for thought for both the Council of Europe and the United Nations. We are convinced that the study will make us stronger in our fight against trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs.

Maud de Boer-Buquicchio
Deputy Secretary General of the Council of Europe

Rachel Mayanja
Assistant Secretary-General of the United Nations and Special Adviser on Gender Issues and Advancement of Women

Executive summary

In 2008, the Council of Europe and the United Nations agreed to prepare a *Joint Study on trafficking in organs, tissues and cells (OTC) and trafficking in human beings for the purpose of the removal of organs*. This Joint Study has been prepared in the framework of the co-operation between the two international intergovernmental organisations, in particular in keeping with the United Nations General Assembly *Resolution on Co-operation between the United Nations and the Council of Europe* (A/RES/63/14), which specifically states:

> "[The General Assembly] *Takes note with appreciation of the entry into force on 1 February 2008 of the Council of Europe Convention on Action against Trafficking in Human Beings, to which any non-member State of the Council of Europe may accede after having obtained unanimous consent of the parties to the Convention, commends the enhanced co-operation between the United Nations and the Council of Europe in this regard, and expresses its appreciation for the preparation of a joint study on trafficking in organs, tissues and cells and trafficking in persons for the purpose of the removal of organs*".

The present Joint Study noted, first of all, that trafficking in human beings for the purpose of organ removal was a small part of the bigger problem of trafficking in OTC. Secondly, the Joint Study pointed out the existence of widespread confusion in the legal and scientific community between "trafficking in OTC" and "trafficking in human beings for the purpose of the removal of organs". Thirdly, the Joint Study underlined that the solutions for preventing the two types of trafficking had to be different because the "trafficked objects" are different: in one case the "organs, tissues and cells" and in the other case the "person him/herself" who is trafficked for the specific purpose of removing his/her organs. One of the major aims of this Joint Study is therefore to distinguish between trafficking in OTC and trafficking in human beings for the purpose of organ removal.

This Joint Study only covers trafficking in OTC for the purpose of transplantation. Other purposes of trafficking in OTC are outside the scope of the Joint Study. The starting point of the Joint Study is the prohibition of making financial gains with the human body or its parts. This principle was established for the first time in a legally binding instrument in Article 21 of the 1997 *Council of Europe Convention on Human Rights and Biomedicine [CETS No. 164]*: "The human body and its parts shall not, as such, give rise to financial gain". The principle was then reaffirmed in the 2002 *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [CETS No. 186]*. Article 22 of the Protocol states: "Organ and tissue trafficking shall be prohibited". The principle of the prohibition of making financial gains with the human body is also very important in order not to jeopardise the donation system based on altruism, both from living and from deceased donors, which must be the basis of the organ transplantation system. Given that trafficking in organs mainly exists because of the lack of available organs, it is also essential to take the organisational measures needed to increase the availability of organs for transplantation.

Taking into account the above-mentioned considerations, the main conclusions and recommendations of this Joint Study could be summarised as follows:

- The need to distinguish clearly between "Trafficking in OTC" and "Trafficking in human beings for the purpose of the removal of organs". The two are frequently confused in public debate and in the legal and scientific community. This leads to general confusion and consequently hinders effective efforts to combat them and also to provide comprehensive victim protection and assistance.
- The principle of the prohibition of making financial gains with the human body or its parts should be the paramount consideration in relation to organ transplantation. All national legislation concerning organ transplantation should conform to this principle.
- The need to promote organ donation and establish organisational measures to increase organ availability. Preference should be given

to deceased organ donation, which should be developed to its maximum therapeutic potential. In addition, there is a need to extend worldwide the organisational and technical capacity for the transplantation of organs.

- The need to collect reliable data on trafficking in OTC and on trafficking in human beings for the purpose of organ removal. There is limited knowledge of the two issues since little information is available from official sources. The information about the number of victims and trafficked OTC therefore remains rather fragmentary. This hinders both the quantification of the two and also their qualitative description. The data should be disaggregated by sex in order to assess whether and to what extent the processes disproportionately affect women and girls. States should make efforts in terms of data collection in relation to both problems.
- The need for an internationally agreed definition of "Trafficking in organs, tissues and cells". This Joint Study did not aim to provide a definition of "Trafficking in OTC". Such a definition should be agreed upon at international level with the involvement of all the relevant players. While underlining that all national systems should be based on the principle of the prohibition of making financial gains with the human body or its parts, the starting point for such a definition should be the idea that any organ transaction outside the national systems for organ transplantation should be considered organ trafficking. It is therefore recommended that an international legal instrument be prepared, setting out a definition of "Trafficking in OTC" and the measures to prevent such trafficking and protect the victims, as well as the criminal-law measures to punish the crime.
- "Trafficking in human beings for the purpose of the removal of organs" is included in the definition of trafficking in human beings in the *Council of Europe Convention on Action against Trafficking in Human Beings* [CETS No. 197] and in the United Nations *Protocol to Prevent, Suppress and Punish Trafficking in Persons, especially Women and Children, Supplementing the United Nations Convention against Transnational Organised Crime*. Indeed, the definition of trafficking in human beings set out in both legal instruments explicitly states that exploitation also includes the removal of organs. The principles and measures applicable to other forms of exploitation of trafficking in human beings must also be applied to combat this type of trafficking for organ removal. There is no need for the further development of a legally binding international instrument at universal or regional level. All relevant aspects for preventing and combating trafficking in human beings for organ removal are set out in the above-mentioned legally binding international instruments.

I. Introduction

In 2008, Maud de Boer-Buquicchio, Deputy Secretary General of the Council of Europe, and Rachel N. Mayanja, Assistant Secretary-General of the United Nations and Special Adviser on Gender Issues and Advancement of Women, agreed that it would be helpful to prepare this *Joint Council of Europe-United Nations Study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs*. The work has been carried out in the framework of co-operation between the two international intergovernmental organisations, in particular in keeping with the United Nations General Assembly *Resolution on Co-operation between the United Nations and the Council of Europe* (A/RES/63/14), which specifically states:

> "[the General Assembly] Takes note with appreciation of the entry into force on 1 February 2008 of the Council of Europe Convention on Action against Trafficking in Human Beings, to which any non-member State of the Council of Europe may accede after having obtained unanimous consent of the parties to the Convention, commends the enhanced co-operation between the United Nations and the Council of Europe in this regard, and expresses its appreciation for the preparation of a joint study on trafficking in organs and tissues, including trafficking in persons for the purpose of the removal of organs.

Indeed, the starting point for the preparation of this Joint Study was the acknowledgment that trafficking in human beings for the purpose of organ removal had never been the subject of in-depth studies despite the fact that this form of exploitation is covered by the definition of trafficking in human beings in the *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organised Crime* (hereafter the United Nations Trafficking in Persons Protocol) and the *Council of Europe Convention on Action against Trafficking in Human Beings* [CETS No. 197] (hereafter the Council of Europe Anti-Trafficking Convention). However, it quickly became obvious, first of all, that trafficking in human beings for the purpose of organ removal was a small part of the bigger problem of trafficking in organs, tissues and cells (OTC) and therefore the former could not be examined without the latter. Secondly, the existence of serious confusion in the legal and scientific communities between "trafficking in OTC" and "trafficking in human beings for the purpose of the removal of organs" was identified. Thirdly, the solutions for preventing both types of trafficking should necessarily be different because the "trafficked objects" are different: in one case the "organs, tissues and cells" and in the other case the "person him/herself" who is trafficked for the specific purpose of removing his/her organs. To express this idea in legal terms, it could be said that trafficking in OTC differs from trafficking in human beings for the purpose of organ removal in one of the constituent elements of the crime – the object of the criminal offence. In the former case, the object of the crime is the organs, tissues and cells, while in the latter case it is the trafficked person. It was therefore decided to enlarge the scope of the Joint Study from trafficking in human beings for the purpose of organ removal and also cover trafficking in OTC.

Following this decision and because in public debate, in publications and in legal documents the issues are often confused or dealt with together, one of the main aims of this Joint Study is to distinguish between trafficking in OTC and trafficking in human beings for the purpose of organ removal. Some trafficking in OTC may originate in trafficking in human beings and will therefore fall within the scope of the United Nations Trafficking in Persons Protocol and the Council of Europe Anti-Trafficking Convention. But trafficking in OTC is much broader in scope than trafficking in human beings for the purpose of organ removal. Indeed, in the broader context of trafficking in OTC, trafficking in human beings for the purpose of organ removal might be considered a marginal phenomenon. On the other hand, trafficking in human beings covers types of exploitation other than the removal of organs and is therefore more than an issue of trafficking in OTC. Trafficking in human beings also involves a combination of three basic elements (action, means and purpose) which may not neces-

sarily be present in cases of trafficking in OTC.

In addition to the unequal distribution of wealth in the world, it is widely recognised that the main root cause of trafficking in OTC and trafficking in human beings for the purpose of organ removal is shortage of organs for transplantation purposes. For this reason it was decided to focus on the analysis of trafficking particularly in relation to transplantation of OTC while omitting from the scope of the report embryos, gametes, blood and blood derivatives. It was agreed to devote a section of the report to an overview of donation for the purpose of transplantation of OTC and a comprehensive review of the principles set at international level in this regard.

The principle that it is not permissible for the human body or its parts as such to give rise to financial gain is established Council of Europe legal *acquis* and is the starting point of this Joint Study. It was first stated internationally in Resolution (78) 29 of the Committee of Ministers of the Council of Europe and was confirmed, in particular, by the final declaration of the 3rd Conference of European Health Ministers (Paris, 1987) before being definitively laid down in Article 21 of the 1997 *Convention on Human Rights and Biomedicine* [CETS No.164]: "The human body and its parts shall not, as such, give rise to financial gain". At United Nations level, there is no legally binding instrument which sets out the principle of the prohibition of making financial gains from the human body or its parts. However, the World Health Organization *Guiding Principles on Human Cell, Tissue and Organ Transplantation,* which clearly include this principle, have been incorporated in many professional standards and laws and are not only widely recognised but also basically undisputed in terms of standard-setting. Moreover, in May 2004 the 57th World Health Assembly in *Resolution WHA57.18 on Human Organ and Tissue Transplantation* urged member states "to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the international trafficking in human tissues and organs". The principle of the prohibition of making financial gains with the human body is also essential in order not to jeopardise the donation system which must be the basis of the organ transplantation system.

This Joint Study has acknowledged that there is no internationally agreed definition of trafficking in OTC, although several attempts to provide a definition have been made by international bodies and initiatives. Under some of these definitions, trafficking in OTC is deemed to occur when profit is the main intention linked to the act of donation and transplantation. Under other definitions, any illicit action related to donation and transplantation according to the current national or international standards is deemed to constitute trafficking in OTC. Lastly, some of the definitions of trafficking in OTC correspond to the definition of trafficking in human beings for the purpose of organ removal, which once again highlights the lack of distinction between the two types of crime.

For the purpose of facilitating the reading of this Joint Study, **trafficking in OTC** could preliminarily be described as follows: trafficking in OTC occurs when there is (a) the illicit removal, preparation, preservation, storage, offering, distribution, brokerage, transport or implantation of organs, tissues or cells (cells for the purpose of therapeutic transplantation); and (b) the possession or purchase of organs, tissues or cells with a view to conducting one of the activities listed in (a); solely for financial or other economic gain (for this or a third person's benefit).

This Joint Study seeks to deal with trafficking in OTC and trafficking in human beings for the purpose of organ removal in a comprehensive and holistic way. Both are complex problems which have to be dealt with on a multidisciplinary basis. The study mainly focuses on medical and legal aspects, as this is where the differences and overlaps can best be demonstrated, most efforts have already been made and the effectiveness of the existing measures can be analysed. However, the study is not limited to these aspects, but also encompasses ethical problems and organisational and other measures. In general, it gives an overview of the current legal and factual situation, examines existing measures to combat both forms of crime and explores further avenues to fight them.

The Council of Europe and the United Nations both take a human rights approach to trafficking in OTC and trafficking in human beings for the purpose of organ removal. This Joint Study aims to reflect how this approach has influenced the measures taken up to now and how it could be further developed. A further aim is to give an overview of the current state of affairs from a gender perspective and examine whether trafficking in OTC and trafficking in human beings for the purpose of organ removal have a more serious impact on women and girls. There is a growing concern and a body of evidence that trafficking in human beings has been affecting women and girls disproportionately, as one of the root causes is poverty and discrimination, including sexual discrimination, and women and girls make up the majority of the poor and of victims of sexual violence. The conclusions and findings of the study will provide a basis for examining existing measures to combat trafficking in OTC and trafficking in human beings for the purpose of organ removal and exploring possible further avenues for developing policies and programmes in way that addresses the needs and concerns of both women and men.

This Joint Study has been prepared by scientific and legal experts appointed by the United Nations and the Council of Europe. Statements in the study are based on the research and personal opinions of the authors and do not reflect the official position of the United Nations or the Council of Europe. The scientific experts, appointed by the United Nations, were Arthur Caplan, Chair of the Department of Medical Ethics and Director of the Center for Bioethics at the University of Pennsylvania in Philadelphia (United States of America), and Rafael Matesanz and Beatriz Domínguez-Gil of the Spanish National Transplant Organisation (Organización Nacional de Trasplantes). Mr Matesanz and Ms Domínguez-Gil are both representatives on the European Committee on Organ Transplantation (CD-P-TO). The legal expert, appointed by the Council of Europe, was Carmen Prior, Public Prosecutor (Austria).

The authors were assisted by the Secretariat of the Council of Europe Convention on Action against Trafficking in Human Beings and the Office of the Special Adviser on Gender Issues and Advancement of Women at the United Nations Department of Economic and Social Affairs. Representatives of the secretariats of the World Health Organization and the United Nations Office on Drugs and Crime, as well as the European Directorate for the Quality of Medicines and Healthcare and the Health and Bioethics Department of the Council of Europe, also provided valuable input for the preparation of the Joint Study.

Lastly, in order to facilitate the reading of this Joint Study, some internationally agreed definitions of key terms should already be set out in this introductory section.

Transplantation: the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation, storage and transportation.[1]

Removal: removal from the body of an organ or tissue intended for transplantation, by a surgical procedure or by other means.[2]

Trafficking in human beings, including for the purpose of the removal of organs: the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs.[3]

Abuse of a position of vulnerability: any situation in which the person involved has no real and acceptable alternative but to submit to the abuse involved.[4]

Deceased donor: a human being legally declared, by established medical criteria, to be dead and from whom cells, tissues or organs were recovered for the purpose of transplantation.[5]

Transplant tourism: travel for transplantation if it involves trafficking and/or transplant commercialism or the resources (organs, professionals and transplant centres) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population. Travel for transplantation would be defined as the movement of OTC, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Transplant commercialism would be understood as a policy or practice in which an organ, tissue or cell is treated as a commodity, including by being bought or sold or used for material gain.[6]

1. Article 2 (5) of the Appendix to Council of Europe Rec (2004) 7 on trafficking in organs.
2. Article 2 (4) of the Appendix to Council of Europe Rec (2004) 7 on trafficking in organs.
3. Article 3 of the Protocol to Prevent, Suppress and Punish Trafficking in Persons, especially Women and Children, supplementing the United Nations Convention against Transnational Organised Crime and Article 4 of the Council of Europe Convention on Action against Trafficking in Human Beings.
4. Travaux préparatoires of the negotiations for the elaboration of the United Nations Convention against Transnational Organised Crime and the Protocols thereto, interpretative note regarding Article 3.
5. WHO Glossary of terms on donation and transplantation.
6. Modified from the Declaration of Istanbul on Organ Trafficking and Transplant Tourism. Transplantation 2008; 8: 1013-1018.

II. Overview of organ donation for transplantation purposes

A. Transplantation of organs and tissues

Transplantation: a historical perspective

The first successful kidney transplant was performed at the Peter Bent Brigham Hospital in Boston in 1954 and subsequently led to the awarding of a Nobel Prize.[7] The transplant was performed between identical twins, overcoming the main difficulty in performing successful organ transplants at that time – the immunological discrepancies between donors and recipients – which inevitably led to activation of the alloimmune response, resulting in rejection and loss of the graft.

Since that first successful kidney transplant, organ transplantation has developed into a well-established clinical therapy which saves the life and improves the quality of life of thousands of patients every year. Kidney transplantation now represents the most desirable therapeutic option for patients with end-stage renal disease, providing better outcomes in terms of survival[8] and quality of life[9] than other renal replacement therapies. Kidney transplantation is now considered to have a more favourable cost-effectiveness ratio than dialysis therapy, the alternative treatment for end-stage renal disease.[10]

Nowadays, liver, heart and lung transplantation represent a unique therapeutic approach for patients with end-stage liver, heart and lung failure, although liver transplantation has also been applied in the treatment of specific pathologies not causing end-stage liver failure. Pancreas transplantation of various types has become an option for re-establishing insulin secretion in selected diabetic patients. Small bowel transplantation usually performed as part of a multi-organ transplant is still a relatively rare procedure of mixed efficacy.

The consolidation of organ transplantation is clearly demonstrated by the large number of procedures performed every year. According to data provided by the Global Observatory on Donation and Transplantation,[11] almost 100 000 patients worldwide receive a solid organ transplant every year (Figure 1, page 18). Additionally, a large number and variety of tissues and cells are implanted on a routine basis to treat a wide range of pathologies, many of them life-limiting. The exact number of tissue transplants performed nowadays is unknown, but is considerably higher than the number of organ transplants. The number of tissue transplants done is high because of the large number of tissues that can be transplanted and the many uses to which they can be put. Corneal transplants restore vision; heart valve transplants involve lower morbidity rates than porcine or artificial valves; bone is used to repair damage due to trauma, cancer or degeneration; dural matter transplants are used to protect the brain after traumatic head injury leaves it exposed to infection; joints and tendons are transplanted to restore mobility and independence; and skin is used extensively in the treatment of burns. Fat and other tissue is used both in reconstructive and in cosmetic surgery.

From the first successful kidney transplant back in 1954 to the situation today, where transplantation of all kinds of solid OTC is a routine practice in many countries, several different historical milestones have been achieved. After 1954, various renal transplants were conducted between identical twins, but this option was very limited and patients' needs could only be met in the very fortunate cases of twins. The need to overcome the immunological reaction when transplantation was performed between non-HLA identical persons was the key limiting factor in organ transplantation. The description of azathioprine in the 1960s and its use in combination with steroids made kidney transplantation between close relatives a reality without excessive risks. In 1976, Jean Borel discovered

7. Merrill JP, Murray JE, Harrison JH, Guild WR. Successful homotransplantation of the human kidney between identical twins. J Am Med Assoc 1956; 160 (4): 277-282.
8. Wolfe RA et al. Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. N Engl J Med 1999; 341: 1725-1730.
9. Keown P. Improving the quality of life. The New Target for Transplantation 2001; 72: 567-574.
10. Winkelmayer WC, Weinstein MC, Mittleman MA, Glynn RJ, Pliskin JS. Health economic evaluations: the special case of end-stage renal disease treatment. Med Decis Making 2002; 22: 417-430.
11. Global Observatory on Donation and Transplantation. http://www.transplant-observatory.org/default.aspx.

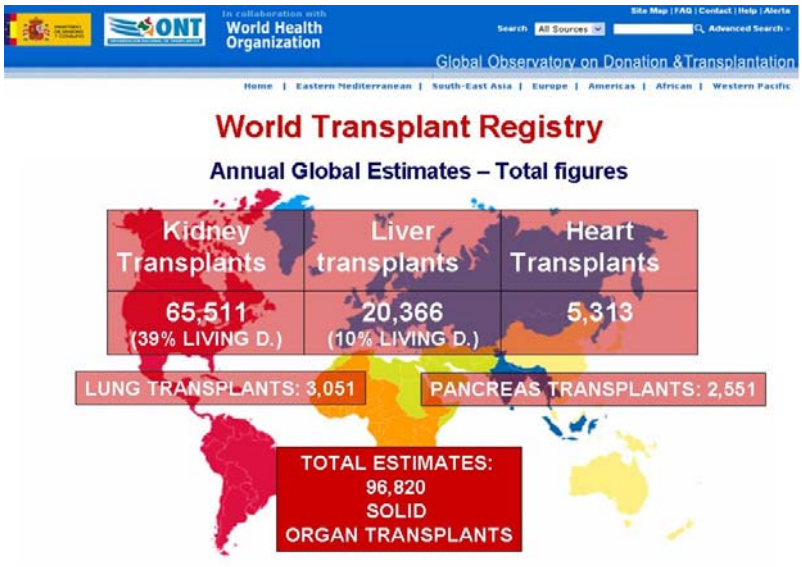


Figure 1. Estimates of the number of solid organ transplants performed annually worldwide, according to the Global Observatory of Donation and Transplantation (http://www.transplant-observatory.org/default.aspx)

the potent immunosuppressive effect of Cyclosporine A. This drug dramatically improved the results of transplantation overall, and from related living donors in particular. Its incorporation in the immunosuppressive armamentarium and the subsequent description and commercialisation of other agents in recent years has enabled the immunological difficulties of transplantation gradually to be overcome in such a way that the importance of HLA compatibility between donors and recipients as a factor impacting on post-transplantation results has gradually been reduced. These developments paved the way for transplantation between genetically unrelated donors and recipients, with extraordinary results.

Alongside the advances in immunosuppression, the development of donation from deceased organ donors has been remarkable. In the early days of organ transplantation, the source of transplantable kidneys was either living donors or deceased donors who had died from cardio-respiratory arrest (non-heart-beating donors or donors after cardiac death). The description of brain death[12] in 1959 and the wide scientific and legal acceptance of its diagnostic criteria resulted in brain death donors [or donors after brain death (DBD)] gradually becoming the main source of solid organ transplants in subsequent years, at least in more developed countries. In many countries, however, cultural, socio-economic and health-care structural factors have prevented the development or consolidation of deceased donation activity. For example, there seems to be a significant link between the Human Development Index (HDI) and deceased donation activity in terms of donors per million population (pmp) (Figure 2, page 19), suggesting that there is a minimum degree of development below which having a consolidated deceased donation programme is highly complex.

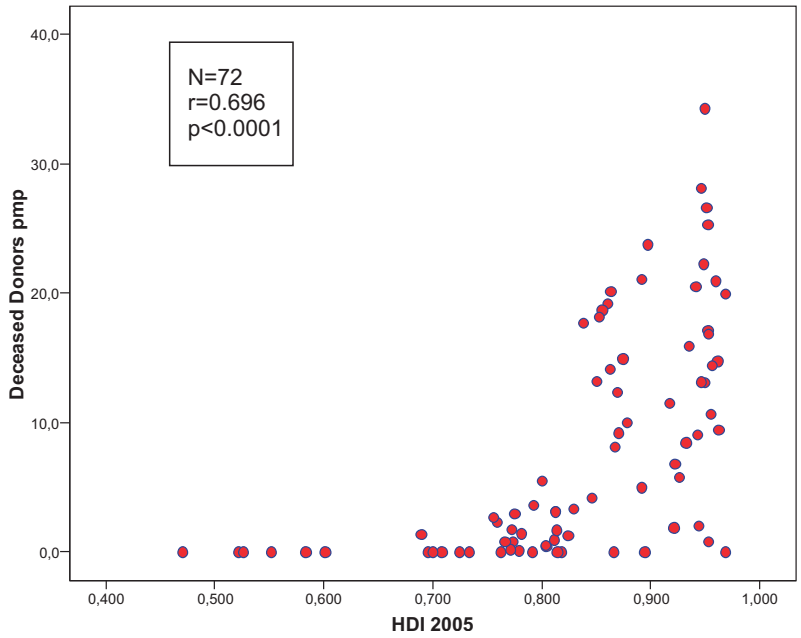
On the other hand, the successful results obtained with living kidney transplantation, which are clearly better than those obtained with kidney transplantation from deceased organ donors, added to the problem of organ shortage, have renewed the interest in living kidney transplantation as a complementary activity to deceased organ donation even in more developed countries. A similar situation has occurred with donation after cardiac death (DCD). In recent years, advances in preservation techniques and better results than those in the very first days of attempting transplants of this kind, combined with the increasing need for organs for transplantation, have led to rapid growth in this type of deceased donation in several countries throughout the world.

12. Mollaret P, Goulon M. *Le coma dépassé* (preliminary memoir). Rev Neurol (Paris) 1959 Jul; 101: 3-15.

Outcomes associated with organ transplantation

Results with nearly all types of solid organ transplantation can be regarded as excellent today. The improved results may be explained by the advances in immunosuppression, combined with advances in surgical and preservation techniques, as well as by the experience acquired by the transplant teams. According to the OPTN/SDRD 2007 Annual Report,[13] in the United States, unadjusted five-year graft survival was 79%, 67.6% and

Figure 2. Link between HDI (2005) and deceased donation activities pmp in several countries (N=79) throughout the world (last available data). Source: Global Observatory on Donation and Transplantation



51% for kidney transplant recipients who received their grafts during the period 1994 to 1999 from a living donor, a deceased non-expanded-criteria donor or a deceased expanded-criteria donor (ECD) respectively. Corresponding figures were 80.2%, 69.8% and 55.1% respectively for patients transplanted from 2000 to 2005. These data also show that results after living kidney transplantation have remained better than those achieved after kidney transplantation from a deceased donor. Indeed, the better results achieved with live kidney transplantation apply even when no genetic relationship exists between the donor and the recipient.[14]

Patient and graft survival after a liver transplant has also gradually improved over time in an impressive way. According to the European Liver Transplant Registry, while 10-year patient and graft survival were 36% and 31% respectively for liver transplants performed from 1968 to 1988, the corresponding figures were 61% and 53% for patients who received their liver grafts after 1988.[15]

The half-life of adult patients who received heart transplants from 1982 to 1991 was 8.8 years, reaching 10.5 years for those patients transplanted from 1992 to 2001, and survival figures also continue to improve for lung transplant recipients according to the International Registry of Heart and Lung Transplantation, with a half-life of 3.9 years for patients transplanted from 1988-1994 to 5.5 years for those patients transplanted from 2000 to 2006.[16]

But challenges regarding post-transplant results remain. In the long run, grafts are lost mainly due to the widely known phenomenon of "chronic rejection" and death with a functioning graft. The main causes of death in the transplanted patients include cardiovascular disease and tumoral diseases. These causes of death are closely related to the chronic use of immunosuppression by recipients, which is still needed today. Transplantation is also linked to a set of other immediate and long-term complications. The inherent risk of transmissible diseases linked to the transfer of any human material, whether organs, tissues or cells, and hence to transplantation should be underlined. Transmission of infectious and tumoral diseases from donors to recipients of their OTC has been widely described in the literature. This risk is usually minimised and controlled through careful medical evaluation of the donor, according to pre-established standards.

13. OPTN/SRTR 2007 Annual Report. OPTN website. Accessible at: http://www.optn.org/. Last access: 26 August 2009.
14. Cecka JM. The OPTN/UNOS Renal Transplant Registry 2003. Clin Transpl. 2003: 1-12.
15. European Liver Transplant Registry website. Accessible at http://www.eltr.org/. Last access: 26 August 2009.
16. The International Society for Heart and Lung Transplantation website. Accessible at: http://www.ishlt.org/. Last access: 26 August 2009.

Organ shortage: a universal problem

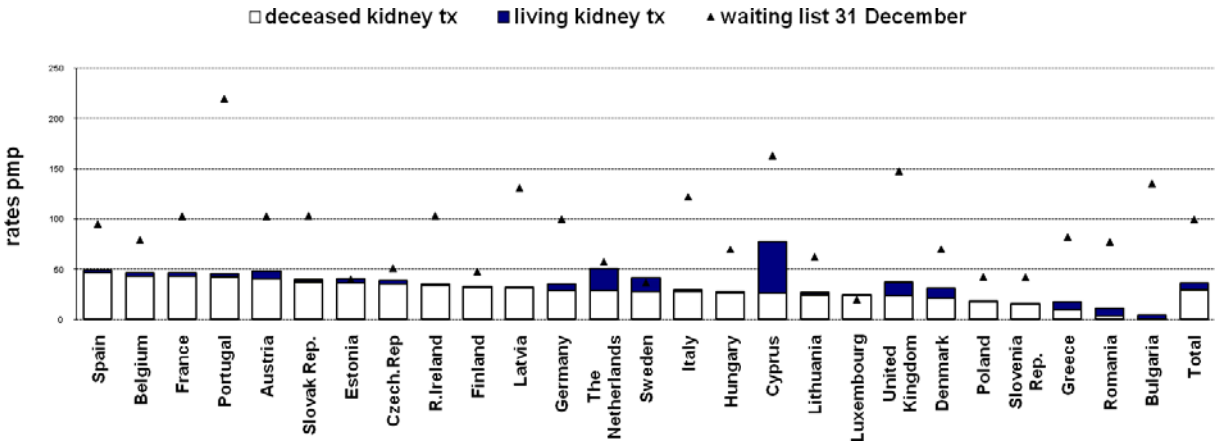
Although many problems still have to be resolved in the field of organ transplantation, the main challenge remains organ shortage, which prevents many patients from receiving the benefits of transplantation. The excellent results achieved with organ transplantation have led to a progressive increase in the number of patients on waiting lists. The lengthening waiting lists worldwide are also linked to the fact that the capacity to

perform transplants is increasing every year as new programmes are opened. In addition, as their skills increase, transplant teams are willing to accept far sicker patients than were put on waiting lists only twenty years ago. Third, as populations age in the developed world, more and more people find themselves afflicted with diseases that lead to organ failure. Fourth, changes in diet and lifestyle are causing significant increases in the incidence of diseases such as diabetes and coronary vessel disease which lead to organ failure and, thus, the need for more transplants. And, lastly, people who have received transplants are living longer but, as a result, they increasingly require retransplantation as the organs they initially received begin to fail. Hence, demand for organs for transplantation is increasing. However, the number of organ donors and organs available for transplantation has never been enough to meet the increasing need for organs. As a result, there is a significant gap between supply and demand in terms of organs to be transplanted.

According to the Council of Europe,[17] at the end of 2007, 58 182 patients were waiting for a kidney, a liver or a heart transplant in the European Union (EU), while only 25 932 corresponding transplant procedures were performed during that year. Figure 3 shows kidney transplantation activity for countries in the EU in relation to the demand for kidneys for transplantation as represented by the number of patients on the list at the end of 2007 for individual countries and for the EU as a whole. Similar figures apply in other areas of the world. In the United States 95 150 patients were on the waiting list for a kidney, liver or heart transplant at the end of that year. That far outstrips the number of kidney, liver and heart transplant procedures performed in the country during 2007: 25 328 transplants.

17. International Figures on Organ Donation and Transplantation – 2007. Newsletter Transplant 2008; 13 (1).

Figure 3. Number of kidney transplant procedures pmp from deceased (white boxes) and living donors (blue boxes) and number of patients pmp on the waiting list for a kidney in countries in the European Union



These figures only show the tip of the iceberg of the universal problem of organ shortage. Waiting list numbers have traditionally been presented as the number of patients waiting at a particular point in the year, not the total number of patients who were on the list at any time throughout a given year. There is also a delicate balance between supply and demand in terms of organs for transplantation. Organ shortage prevents physicians from including some patients on the waiting list, especially those with low expectancies of survival. In contrast, criteria for including patients on the list may be more flexible in countries where procurement of organs is higher.

Lastly, demand for organs for transplantation is expected to increase in the near future, particularly in the case of kidney transplantation. It has been projected that the number of patients with diabetes mellitus will double from the year 2000 to 2030, especially in developing countries.[18] This epidemic of diabetes, added to the ageing of the population, arterial hypertension and obesity is expected to have a significant impact on the prevalence of end-stage renal disease worldwide and hence on the need for kidneys for transplantation.

18. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27 (5): 1047-1053.

While organ shortage for transplantation is a universal problem, it is clear that the systems in place differ substantially in their effectiveness in tackling the problem. Table 1 shows deceased organ donation activity for different regions and major countries throughout the world for 2007.[19] The notable discrepancies observed in deceased organ donation stem from very significant differences between the countries regarding transplantation activity and hence the likelihood of transplantation for their citizens. When these figures are compared, however, some of the differences may be explained by the degree of socio-

19. See note 13, page 19.

Table 1. Deceased donation and transplantation activities pmp in several areas and large countries across the world for 2007

	United States	European Union	Canada	Australia/New Zealand	Iberoamerica
Deceased donors pmp	26.6	16.9	14.8	9.4	5.7
Deceased Kidney Tx pmp	34.8	29.2	22.8	16.2	8.9
Living Kidney Tx pmp	19.9	6	14.4	12.9	7
Liver Tx pmp	21.4	13.4	14.6	7.3	3.2
Heart Tx pmp	7.3	4.2	5.2	2.9	0.7
Lung Tx pmp	4.8	2.6	5.5	3.7	0.2
Pancreas Tx pmp	4.4	1.6	2.2	1.2	0.5

economic development and structural aspects of healthcare systems. Unfortunately, these differences remain when countries with a quite similar background are compared. Table 2, page 22, shows deceased donation and transplantation activity for countries in the EU.[20] It can easily be seen that even when countries with a quite similar degree of development are compared, such important differences regarding deceased donation activity remain. This leads to the conclusion that some systems in place are more effective than others in tackling the universal challenge of shortage of organs for transplantation. Subsequent differences regarding transplantation might also depend on structural differences such as the presence of a specific transplant programme or the existence of organ exchange agreements, but the link between donation and transplantation rates is clear.

20. See note 13, page 19.

The dire consequences of organ and tissue shortage

The most serious consequence of the shortage of organs to meet the demand for transplantation is the fact that many patients will never be placed on the waiting list. There are clear variations in the figures for transplantation throughout the world (Figure 4, page 23).
These differences largely depend on variations in the prevalence and incidence of end-stage organ diseases throughout the world and the existence of basic infrastructure in the countries for the actual performance of transplantation. However, they may also be explained by variability in the flexibility of inclusion criteria, largely due to the problem of shortage of organs for transplantation, as already pointed out. For patients on the lists, organ shortage results in longer waiting times, meaning patients may deteriorate or even die while waiting for an organ. These deaths are especially tragic, as many could be prevented if there were more organs available to transplant. Since there are not, hard choices have to be made about who will live and who will die.

According to data collected by the Council of Europe, more than 4 000 patients died in the EU while waiting for a kidney, liver, heart or lung during 2007, which means that 12 EU citizens died every day while waiting to be transplanted (Figure 5, page 23). This is by far the most serious consequence of the shortage of organs for transplantation.

Another less well-known consequence of long waiting times is the fact that time spent waiting for a kidney transplant has proven to have a negative impact on graft survival after kidney transplantation.[21] The longer the time spent on the waiting list, the worse the outcome results are after kidney transplantation, whether from a living or from a deceased organ donor.

21. Cecka JM. The OPTN/UNOS Renal Transplant Registry 2003. Clin Transpl 2003; 1-12.

Another major problem stemming from organ shortage is the fact that alternatives to kidney transplantation in terms of renal replacement therapies, i.e. dialysis, produce poorer results and are more expensive than kidney transplantation. The cost of haemodialysis *per* patient is lower than transplantation in the first year. However, the cost related to kidney transplantation falls sharply after the first year, producing a more favourable cost-effectiveness ratio than dialysis treatment. Moreover, the greater cost-effectiveness of kidney transplantation has been demonstrated both in developed and also in developing countries.[22] [23]

Lastly, the desperation of patients waiting for transplants leads to another tragic consequence, namely trafficking in OTC and the most terri-

22. Shakuja V, Sud K. End-stage renal disease in India and Pakistan: Burden of disease and management issues. Kidney Int Suppl 2003; (3): p115-8.
23. Rizvi SA, Naqvi SA. Need for increasing transplant activity: a sustainable model for developing countries. Transplant Proc 1997; 29 (1-2): 1560-1562.

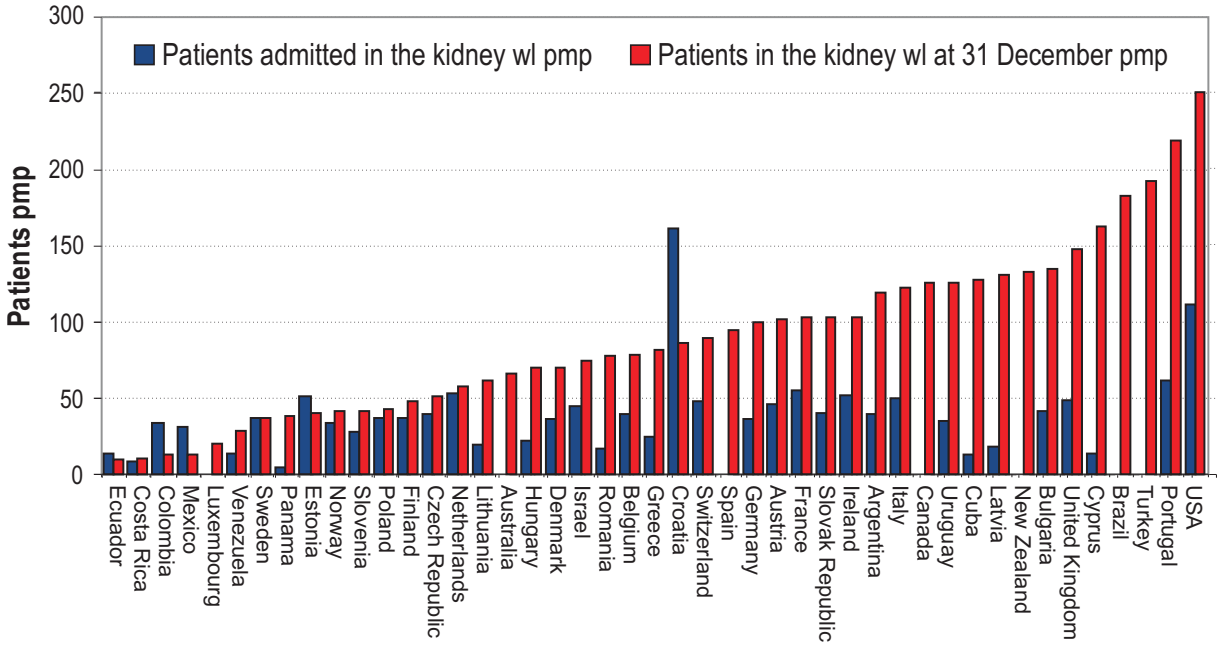
Table 2. Deceased donation and transplantation activities pmp in countries within the European Union 2007

	Deceased donors pmp	Deceased kidney Tx pmp	Living kidney Tx pmp	Liver Tx pmp	Heart Tx pmp	Lung Tx pmp	Pancreas Tx pmp
Spain	34.3	45.9	3	24.6	5.3	4.1	1.7
Belgium	28.2	42.4	4	25.2	7	8.8	1.7
France	25.3	42.3	3.7	16.8	6.1	3.5	1.5
Portugal	23.9	42.2	3.5	25.1	4.8	0.4	1.8
Austria	22.3	40.5	7.5	14.3	6.9	9.9	3
Czech.R	21.1	35	3.3	11.2	6.7	1.2	2.6
Ireland	21	33.6	1.2	14	1.7	1	1.2
Italy	20.5	27.2	1.7	18.4	5.4	1.9	1.3
Latvia	18.7	31.3	0.4	0	1.3	0	0
Finland	17.2	31	1	10	4.2	2.8	-
Germany	16	28.4	6.9	14	5	3.5	1.6
Hungary	15	26.3	1.7	4.1	2.2	-	0.5
Sweden	14.5	27.9	13.4	14.8	5	4.7	1.1
Lithuania	14.1	24.4	2.7	2.7	4.4	12	-
Netherlands	16.9	28.4	22	9.1	3.2	4	1.7
Denmark	13.2	21	10.2	7.9	5.3	6	-
Estonia	13.2	21	10.2	7.9	5.3	6	-
United Kingdom	13.2	23.5	13.4	10.7	2.3	2	4.1
Slovenia	11.4	14.9	0.5	5	5.5	-	-
Poland	9.2	17.1	0.6	5.1	1.7	2	0.6
Greece	5.8	9.2	7.9	2.9	0.5	0.2	-
Luxembourg	2.1	25.2	0	0	-	-	-
Romania	1.7	3.3	7.2	1.5	0.4	0	0
Bulgaria	1.3	1.5	2.2	1	0.4	0	0
Cyprus	-	25.7	51.4	-	-	-	-

ble form of trafficking in this regard, trafficking in human beings for the purpose of organ removal. Organ transplantation exists in a world of extreme economic disparity. There are also huge inequities in the access which people throughout the world have to transplantation services. For a variety of reasons, many countries have also not engaged in policies that would enable them to become self-sufficient in terms of the supply of OTC for medical purposes. The great scarcity affecting the supply of organs and the growing demand for organs and tissues as medicine advances produce circumstances in which trafficking in human beings to obtain organs, organ trafficking and what is sometimes referred to as transplant "tourism" can flourish. These circumstances also encourage trafficking since the rich can shorten the time they have to wait for a transplant by exploiting the disadvantages faced by the very poor. Lack of organs as an immediate solution for patients in need leads them to search for alternative solutions and cut corners in order to secure a transplant. Criminal groups take advantage of this desperation which is added to that stemming from poverty and misery in many areas of the world. All these factors provide the basis for the development of these practices as a modern horror added to the endless list of tragic disasters affecting the whole world.

However, the relationship between organ shortage and these phenomena might be even more complex, with additional elements contributing to their emergence and continuation over time. One of the technical solutions for tackling shortage of organs for transplantation is the use of so-called expanded-criteria donors (ECD) (see below), whose age and/or

Figure 4. Number of patients pmp placed on the waiting list (blue bars) and on the waiting list at the end of the year (red bars) for a kidney transplant in several countries of the world in 2007. Source: Council of Europe. Newsletter Transplant



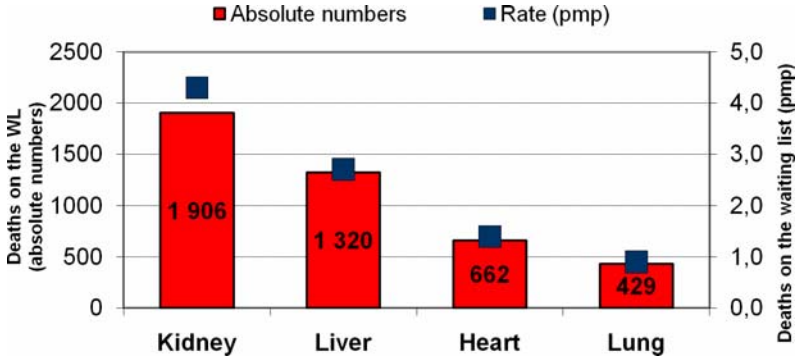
co-morbidity characteristics are known to have a negative impact on the quality of organs for transplantation. The increase in the use of these donors is a strategy which partially explains the higher levels of transplantation activity in several countries.

The need for the use of ECD also stems from the fortunate decrease in deaths due to traffic accidents in many developed countries and hence the need to adapt to the new profile of organ donors in order to meet the transplantation needs of the population. While it is quite clear that the transplantation of organs from these donors produces very acceptable results in appropriate recipients,[24] it is also true that results in the long term are poorer than those obtained with more ideal donors and far poorer than results obtained with living donors in the case of kidney transplantation. Better results involving kidney transplantation from living donors are achieved even when no genetic relationship exists between donors and recipients.[25] Patients might therefore prefer to search for a living donor, especially because of changes in the profile of deceased organ donors in their countries. Moreover, many would opt to look for a living donor outside their immediate environments because of the lack of willing relatives or because of a desire to avoid risks or putting pressure on loved ones, which once again may lead to trafficking.

24. Pascual J, Zamora J, Pirsch JD. A systematic review of kidney transplantation from expanded criteria donors. Am J Kidney Dis 2008; 52 (3): 553-586.

25. Collaborative transplant study website. Accessible at: http://www.ctstransplant.org/. Accessed 26 August 2009.

Figure 5. Deaths (absolute figures and pmp) on the waiting list for a kidney, liver, heart or lung transplant in the European Union. 2007



Solving the organ and tissue shortage

Live donation on its own cannot solve the transplantation needs of a population, one reason being that the transplantation needs for specific organs and tissues will never be met through live donation. Dealing effectively with organ shortage requires the development of a deceased donation programme to enable each country to reach its maximum therapeutic potential from deceased donors. Live donation should therefore be generally regarded as a complement to deceased donation activity.

This section is intended briefly to describe a set of measures that have been developed to increase deceased donation rates and maximise organ and tissue availability from deceased organ donors.

Over the years, various conventional approaches for tackling the scarcity of organs and donors for transplantation have proven to be of limited usefulness. One approach involves changing the legal framework regarding the type of consent required to proceed with organ donation, moving from an expressed (opt-in) to a presumed (opt-out) system. The idea behind the model of expressed consent is that the person has to express his/her will to donate explicitly during his/her lifetime. This approach may be modified in such a way that if the donor did not communicate his/her will during his/her lifetime, consent may be obtained from relatives or other persons who had a close relationship with the donor. Applying the concept of expressed consent means that, if the will of the donor is unknown and no relatives are available to make a decision, organs cannot be recovered. In contrast, the model of presumed consent is based on a refutable presumption and a person who does not wish to become an organ donor after death must express his/her objection during his/her lifetime in accordance with the provisions of national legislation.

There are conflicting reports about the existence of significantly higher deceased donation rates in countries with a presumed consent policy, and about the impact of a change from an opt-in to an opt-out system.[26] [27] [28] This basically stems from the fact that presumed consent is not usually strictly applied. In the context of two projects funded by the European Commission, ALLIANCE-O and DOPKI, it was noticed that the two policies do not differ substantially in day-to-day practice.[29] In many European countries with presumed consent, relatives are frequently approached in order to clarify the deceased person's wishes regarding organ donation and if the wishes of the deceased are at odds with those of the relatives, the will of the latter is always respected. Of course, this practical similarity between the two systems might not be the case for non-European countries.

Other conventional approaches for tackling organ shortage have also proven to be of limited usefulness. Promotional campaigns, for example involving advertisements on billboards or buses, seem to have a transient impact, if any, on deceased donation rates, although they may help to increase awareness of the need for donation among the general population.[30] Lastly, the development of tools which may facilitate the expression of the wishes of the deceased regarding organ donation during lifetime may be regarded as a social tool that is far from being effective in increasing donation rates.

Today, it is widely recognised that proper organisation of the process of deceased donation, optimising every step (see below), is the right approach to deal efficiently with the shortage of organs for transplantation. Some technical initiatives are also proving to be highly useful as a means of increasing the availability of organs.

26. Low HC, Da Costa M, Prabhakaran K, Kaur M, Wee A, Lim SG, Wai CT. Impact of new legislation on presumed consent on organ donation on liver transplant in Singapore: a preliminary analysis. Transplantation 2006; 82: 1234-1237.
27. Hitchen L. No evidence that presumed consent increases organ donation. BMJ 2008; 337: 1614.
28. The potential impact of an opt-out system for organ donation in the United Kingdom – An independent report from the Organ Donation Taskforce. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312. Last access: 26 August 2009.
29. White Paper ALLIANCE-O (European Group for Co-ordination of National Research Programmes on Organ Donation and Transplantation 2004-2007). Web page ALLIANCE-O. Available at: http://www.alliance-o.org/news/. Last accessed: 26 August 2008.
30. Frates J, Bohrer GG, Thomas D. Promoting organ donation to Hispanics: the role of the media and medicine. J Health Commun 2006; 11: 683-698.

The process of deceased donation: organisational and technical initiatives for dealing with organ shortage

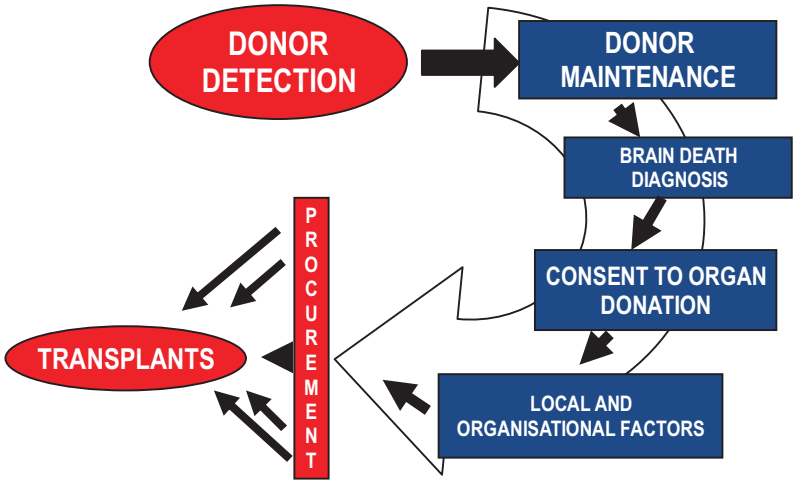
Organisational initiatives to increase donation and transplantation activities

Deceased donation activity is primarily based on DBD. It should be stressed that no more than 1% of deceased individuals and no more than 3% of people who die in hospital fall into this category. The number of potential brain-dead donors is therefore limited. However, it is difficult to attain the potential of DBD, since organ donation and procurement is a very delicate and complex process that requires the co-operation of

many players and can easily be interrupted at any time.[31] Moreover, the whole process must take place in a very short period of time, as organs with long ischaemic times (periods with no blood supply) are unsuitable for transplantation. This compounds the weaknesses of the process itself. Several basic steps may be identified here (Figure 6). The different steps are areas of potential loss of donors and organs for transplantation. Because of its nature and characteristics, developing an effective deceased donation programme requires proper organisation of the process described. In general terms, it should be underlined that there is no lack of potential donors, but a failure to identify them and subsequently activate and effectively develop the deceased donation process.

31. Meeting the organ shortage: current status and strategies for improvement of organ donation. A European consensus document. Council of Europe web page. Last accessed: 26 August 2009.

Figure 6. Steps in the process of donation after brain death



The importance of organisational measures as applied to deceased organ donation has been stressed by the Council of Europe, the European Union and the Iberoamerican Network/Council of Donation and Transplantation (see below, page 45) and has been clearly reflected in consensus documents, recommendations and specific actions and activities. Moreover, organisational aspects are the key characteristics of models that are benchmarks at a global level because of their high deceased donation rates and transplantation activity, for instance the Spanish Model of Donation and Transplantation.[32] Some of these organisational measures are summarised in this section.

The establishment of a network of procurement hospitals under the umbrella of a supranational organisation is the recommended structure. The appointment of "key donation professionals" at procurement hospitals with the main responsibility of developing a proactive detection of potential donors is identified as a basic requirement for improving deceased donation rates.[33] [34] Other responsibilities for these key figures (also called "Transplant Co-ordinators") would include increasing the level and quality of deceased donation, including educational, training and research activities. In contrast, there is no such clear agreement on the profile of these key figures and their position with regard to the procurement hospitals. As stated in several recommendations,[35] the ideal situation would involve in-hospital figures with a close relationship with the intensive care unit, which would facilitate detection of potential donors and subsequent activation of the process. In practice, the profile of these figures varies greatly between countries, in terms both of their position with respect to the procurement hospitals and of their professional backgrounds.

The need for a supra-hospital organisation or agency stems from the specific nature and characteristics of the deceased donation and transplantation process and is regarded as one of the basic requirements for guaranteeing the success of a donation programme. However, the structure and responsibilities of such organisations vary greatly between countries. The differences depend on their origin and the background and profile of the professionals who founded and manage them, as well as on economic and health-structure issues in the relevant countries, among other factors. Although there is no single formula to guarantee the success of a programme, in general terms, the ideal situation is for the body to be in charge of organ allocation and distribution and also to act as a support agency for the entire process of deceased organ donation.

32. Matesanz R, Domínguez-Gil B. Strategies to optimise deceased organ donation. Transplant Rev 2007; 21: 177-188.

33. See note 29, page 24.
34. See note 31, page 25.
35. Rec (2005) 11 of the Committee of Ministers to member states on the role and training of professionals responsible for organ donation (transplant "donor co-ordinators").

Supporting the deceased donation process could involve a wide range of actions and activities, many of which are clearly indicated in the corresponding Council of Europe recommendation.[36] Focusing on the need to solve the problem of organ shortage, a supra-hospital organisation should, if necessary, evaluate and propose legislative measures in order to ensure a legislative framework in line with current scientific knowledge with regard to donation and transplantation. It ought to act as a genuine interface between the political and the technical level. Logistical co-ordination of all activities in the process should be performed on a timely and effective manner by the body, in co-operation with procurement and transplantation centres. Material and human resources are therefore needed and activities should be developed without improvisation and according to pre-established protocols so as to ensure that the maximum number of organs is obtained and the organs and/or teams are transported effectively and quickly. In short, it is essential for the concept of "quality" to be incorporated in the process of deceased donation.

In close liaison with the procurement hospitals, the development of specific programmes aimed at detecting, evaluating and correcting problems in the donation process is vital. In line with this need, the development of quality assurance programmes allowing estimation and monitoring of donation potential, areas for improvement and overall effectiveness (or performance) in the deceased donation process has also been recommended.[37] Lastly, promoting research, training professionals involved directly or indirectly in the donation process, educating people and communicating properly seem to be further requirements for tackling the problem of shortage of organs for transplantation. In particular, education and communication are highly relevant activities for creating positive attitudes in society towards donation and transplantation and building trust in the system, both of which are needed to facilitate the involvement of society.

Technical initiatives to increase donation and transplantation activities

There are also technical initiatives that have been considered as a means of increasing donation and transplantation rates: the use of ECD and of special surgical techniques to maximise the use of organs for transplantation, for instance split and domino transplantation and double kidney transplantation with kidneys from ECD. These strategies are outside the scope of this study, but we will nevertheless look at ECD, as they are becoming quantitatively significant in countries with well developed deceased donation programmes.

To increase the supply of organs for transplantation, the medical contra-indications for donations have been altered over time. Increasing use is now made of organ donors who had not traditionally been accepted as such because of specific pathologies or conditions. These donors have been termed ECD, or sometimes marginal or suboptimal donors.

Several definitions have been provided for ECD. The United Network for Organ Sharing (UNOS) defines ECD as persons with one or more of the following factors: age over 55 years, over ten-year history of hypertension, over ten-year history of diabetes mellitus, DCD and cold preservation time over 36 hours.[38] ALLIANCE-O gave a more general definition of ECD, as persons potentially associated with poorer results in the recipients when compared with cases of recipients receiving their organs from traditional or more ideal donors.[39] This would include extreme age and donors with potentially transmissible diseases (infections and neoplasias) or other pathologies. The conditions and pathologies in question have traditionally been regarded as formal contra-indications for organ donation. However, there is increasing evidence that when organs from these donors are used in appropriate and specific conditions the results may be very acceptable and even similar to those obtained with organs from more ideal donors. The use of organs from ECD has therefore gradually become a real way of expanding the donor pool and they actually represent a very significant percentage of deceased organ donors in many countries. For example, more than 40% of deceased organ donors in countries such as Italy and Spain are aged 60 years or over (DOPKI data, not published). As previously stated, using these organs is becoming essential in order to maintain transplantation activity, especially in countries where deaths due to cranioencephalic traumatisms overall and in young people in particular are fortunately decreasing over time.

Consistently discarding organs from ECD may worsen the shortage of organs for transplantation, but consistently accepting them may involve an element of risk to the recipient outcome in terms of morbidity and mortality and a decrease in graft survival, unless they are used in very specific conditions. The decrease in graft survival due to the use of ECD may also worsen the imbalance between organ supply and demand, since loss of function of a previous graft is increasingly becoming a cause of individuals returning to the waiting lists. These peculiarities raise a series of ethical considerations which are currently a subject of debate.

36. Recommendation Rec (2006) 15 of the Committee of Ministers to member states on the background, functions and responsibilities of a National Transplant Organisation (NTO).
37. Recommendation Rec (2006) 16 of the Committee of Ministers to member states on quality improvement programmes for organ donation.
38. Ojo A et al. Survival in recipients of marginal cadaveric donor kidneys compared with other recipients and wait-listed transplant candidates. J Am Soc Nephrol 2001; 12: 589-597.
39. See note 24, page 23.

Non-heart beating donation (donation after cardiac death)

As mentioned above, in the early days of organ transplantation, the source of transplantable kidneys was either living donors or deceased donors who had died from a cardio-respiratory arrest. However, wide acceptance of the brain death definition and criteria meant that the use of organs from brain death donors subsequently almost fully replaced the use of the former category. The shortage of organs for transplantation, combined with promising results with kidney transplants from these donors, has renewed interest in obtaining organs from DCD. This has led to several conferences and meetings which have sought to address the inherent technical, ethical and legal issues.[40] [41] [42] While activity with DCD has increased in the United States, activity in this area is very limited in Europe and other regions of the world, with some exceptions. In 2007, only five European countries actually did record a significant number of DCD: 186 in the United Kingdom, 114 in the Netherlands, 88 in Spain and 39 in Belgium and France. These low figures are probably a reflection of the legislative, ethical and overall organisational and technical difficulties and dilemmas that this activity involves.

There are several technical and organisational issues that increase the complexity of DCD when compared to DBD. Moreover, while proven to be quite successful with proper donor selection after kidney[43] or even lung[44] transplantation, results after liver transplantation are still a matter of concern. These poor results have improved through careful donor selection, but are still worse than those obtained with DBD. Although the results have improved compared to the first experiences, they are still unsatisfactory and research is under way in order to improve them. While there are many challenges in the field of DCD, it is regarded as a useful and realistic approach for expanding the donor pool. However, concern has lately arisen because of its potential negative impact on DBD, as described in some countries.[45]

40. Kootstra G. The asystolic, or non-heartbeating, donor. Transplantation 1997; 63: 917-921.
41. Donation after cardio-circulatory death. A Canadian Forum. Report and Recommendations. Canadian Critical Care Society. Canadian Society of Transplantation. Feb. 17-20-2005 Vancouver, British Columbia ISBN O-9738718-06 July 2005.
42. Bernat JL, D'Alessandro AM, Port FK et al. Report of a National Conference on Donation after Cardiac death. Am J Transplant 2006; 6: 281-291.
43. Sánchez-Fructuoso AI, Marques M, Prats D, Conesa J, Calvo N, Pérez-Contín MJ, Blazquez J, Fernández C, Corral E, Del Río F, Núñez JR, Barrientos A. Victims of cardiac arrest occurring outside the hospital: a source of transplantable kidneys. Ann Intern Med 2006; 145: 157-164.
44. De Antonio DG, Marcos R, Laporta R, Mora G, García-Gallo C, Gámez P, Córdoba M, Moradiellos J, Ussetti P, Carreño MC, Núñez JR, Calatayud J, Del Río F, Varela A. Results of clinical lung transplant from uncontrolled non-heart-beating donors. J Heart Lung Transplant. 2007; 26: 529-534.
45. Cohen B, Smits JM, Haase B, Persijn G, Vanrenterghem Y, Frei U. Expanding the donor pool to increase renal transplantation. Nephrol Dial Transplant 2005; 20: 34–41.

Living donation

In the first days of successful kidney transplantation, the organs came from living related donors. After the first successful kidney transplant between identical twins was performed in 1954, the first kidney transplant from a non-genetically related donor took place in the Foch Hospital in Paris in 1955. Living donation was the only available source of organs for transplantation until some transplantations with DCD were carried out and the concept of brain death was defined and came to be widely accepted. Over the years, many patients have received transplants from genetically or non-genetically related living donors and, among the latter, from donors with whom they may or may not have a personal relationship. Moreover, while living donors were initially used for kidney transplantation, in recent years, living donation has also become an effective source of organs for liver and, indeed, lung, pancreas and intestine transplantation, although the latter types of organs are not yet quantitatively so significant. Nowadays, in countries with no fully developed deceased donation programmes, transplantation activity mainly or totally relies on live donors. The situation in countries with a reasonably well developed system of deceased donation is different. In particular, living donation is seen in many of these countries as another possibility for increasing the availability of organs for transplantation, at a time of shortage of deceased organ donors. In this context, living donation activity has increased progressively in recent years in many western countries, but still varies significantly between them.

According to data from 2007, living kidney transplant activity in Europe ranged from less than 1 procedure pmp to 51.4 procedures pmp in Cyprus (Table 2, page 22). Living liver donation activity is still limited, since the complexity of partial hepatectomy and the risks for the living donor are clearly higher than those with a nephrectomy. While more than 40% of kidney transplants performed worldwide are from living donors, only about 15% of liver transplants come from this source.[46]

Living donation involves clear benefits for the recipient and the system. First, unlike deceased donation, living donation is an elective procedure. Second, and because of the thorough evaluation and selection of the donor,

46. See note 13, page 19.

the kidney or the liver to be transplanted should be of high quality. Third, damage to the graft in the context of the physiopathological changes of brain death and ischaemia-reperfusion injury is minimised. Fourth, living kidney transplantation may be performed on a pre-emptive basis, avoiding dialysis therapy, with the corresponding savings to the healthcare system and benefits for the recipient in post-transplant outcomes.

As a result, living kidney transplantation is associated with better results than those obtained with kidneys from deceased donors, regardless of the genetic relationship between the donor and the recipient. According to the OPTN, one-year graft survival of kidney transplants is 89% for recipients from deceased donors as against 95.1% for those from living donors, these differences being more pronounced with longer follow-up, with five-year survival rates of 66.5% and 79.7% respectively.[47] Kidney transplantation from living donors also offers benefits in terms of patients' survival compared with deceased donors.[48] As a result, living kidney transplantation is associated with better results than those obtained with kidneys from deceased donors, regardless of the genetic relationship between the donor and the recipient. According to the OPTN, one-year graft survival of kidney transplants is 89% for recipients from deceased donors as against 95.1% for those from living donors, these differences being more pronounced with longer follow-up, with five-year survival rates of 66.5% and 79.7% respectively. Kidney transplantation from living donors also offers benefits in terms of patients' survival compared with deceased donors. Similar results were obtained in the Collaborative Transplant Study.

47. Organ Procurement and Transplantation Network website. Available at: http://www.optn.org/latestData/rptStrat.asp. Last accessed: 26 August 2009.
48. See note 47, page 28.

Survival of living liver-transplanted patients is similar to that described for recipients of livers from deceased donors. However, living liver recipients have been shown to develop higher post-transplantation morbidity. Similar results were obtained in the Collaborative Transplant Study.[49] Survival of living liver-transplanted patients is similar to that described for recipients of livers from deceased donors. However, living liver recipients have been shown to develop higher post-transplantation morbidity.

Living donation must deal with the issue of whether it violates the traditional first rule in medicine, "*primum non nocere*" (above all, do not harm), since no single surgical procedure, including nephrectomy and hepatectomy, is completely risk-free. Living kidney donation is regarded as a relatively low-risk procedure for the donor. Mortality risk has been put at 0.03%, according to several studies.[50] The risk of short-term complications (such as bleeding or infection) is low, although it varies depending on the surgical technique used to perform the nephrectomy in the donor.[51] Living donation must deal with the issue of whether it violates the traditional first rule in medicine, "primum non nocere" (above all, do not harm), since no single surgical procedure, including nephrectomy and hepatectomy, is completely risk-free. Living kidney donation is regarded as a relatively low-risk procedure for the donor. Mortality risk has been put at 0.03%, according to several studies. The risk of short-term complications (such as bleeding or infection) is low, although it varies depending on the surgical technique used to perform the nephrectomy in the donor. Long-term follow-up of living kidney donors has not generally revealed a higher incidence of chronic renal failure or other medical complications than those observed in the general population. However, most of these reports are retrospective, with a significant number of cases not being followed up, and make outcome comparisons in relation to the general population, which might not be the most appropriate basis, since living kidney donors should be considered healthier than the general population. There are also reports of living donors developing a progressive decline in renal function and of some of them becoming kidney transplant candidates in the long run. Long-term follow-up of living kidney donors has not generally revealed a higher incidence of chronic renal failure or other medical complications than those observed in the general population. However, most of these reports are retrospective, with a significant number of cases not being followed up, and make outcome comparisons in relation to the general population, which might not be the most appropriate basis, since living kidney donors should be considered healthier than the general population.[52] There are also reports of living donors developing a progressive decline in renal function and of some of them becoming kidney transplant candidates in the long run.[53]

Besides the medical complications that have been described among living organ donors, some reports have noted the possibility of non-medical complications.[54] For instance, psychological and/or social repercussions of living donation, including financial and occupational disadvantages, have been described in the literature and are a matter of concern for

49. Collaborative transplant study website. Available at: http://www.ctstransplant.org/. Last accessed: 26 August 2009.
50. Matas AJ, Bartlett ST, Leichtman AB, Delmonico FL. Morbidity and mortality after living kidney donation 1999-2001: survey of United States transplant centers, Am J Transplant 2003; 3 (7) 830-834.
51. See note 47, page 28.
52. Ommen ES, Winston JA, Murphy B. Medical risks in living kidney donors: absence of proof is not proof of absence. Clin J Am Soc Nephrol. 2006; 1: 885-895.
53. Delmonico F. A report of the Amsterdam Forum on the Care of the Live Kidney Donor: data and medical guidelines. Transplantation 2005; 79: Suppl 6: S53-S66.
54. Brown RS Jr, Russo MW, Lai M, Shiffman ML, Richardson MC, Everhart JE, Hoofnagle JH. A survey of liver transplantation from living adult donors in the United States. N Engl J Med 2003; 348: 818-825.

the international transplantation community.[55]

The outcome for living liver donors differs from that described for living kidney donors, given the risks related to the performance of a partial hepatectomy, even in a healthy person. The incidence of complications associated with living liver donation varies, depending on the series. However, the level of these complications has proven to be as high as 21% to 28% in some cases.[56] [57] The rate of catastrophic complications, defined as the death of the donor, the need for a liver transplant or the development of a vegetative state has been shown to be not insignificant, with rates of 0.4% to 0.6%.[58]

In this context, there are a range of ethical considerations relating to living donation which have been evaluated within the scope of international legal instruments (see below) and various international consensus conferences aimed at ensuring the protection of the donor, such as the Amsterdam Forum[59] on the living kidney donor and the Vancouver Forum[60] on the living non-kidney donor. Other international recommendations, in particular two recently issued by the Council of Europe, have been produced in the same connection and as a guide for the development of international and national legislation.[61] [62]

55. Reimer J, Rensing A, Haasen C, Philipp T, Pietruck F, Franke GH. The impact of living-related kidney transplantation on the donor's life. Transplantation 2006; 81: 1268-1273.
56. Brown RS Jr, Russo MW, Lai M, Shiffman ML, Richardson MC, Everhart JE, Hoofnagle JH. A survey of liver transplantation from living adult donors in the United States. N Engl J Med 2003; 348: 818-825.
57. Lo CM. Complications and long-term outcome of living liver donors: a survey of 1 508 cases in five Asian centers. Transplantation 2003; 75 (Supp 3): S12-S15.
58. Pruett TL et al. The ethics statement of the Vancouver Forum on the live lung, liver, pancreas, and intestine donor. Transplantation 2006; 81: 1386-1387.
59. The Ethics Committee of the Transplantation Society. The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor. Transplantation 2004; 78 (4): 491-492.
60. See note 58, page 29.
61. Resolution CM/RES (2008) 4 on Adult-to-adult living donor liver transplantation.
62. Resolution CM/RES (2008) 6 on Transplantation of kidneys from living donors who are not genetically related to the recipient.

This section on the transplantation of organs and tissues may be summarised in the following key points:

- Organ transplantation has become a unique therapy able to save the life or increase the quality of life of patients with end-stage organ failure. It is a consolidated therapy which benefits almost 100 000 patients worldwide every year. Activity involving the implant of tissues and cells of human origin also takes place on a large scale and is able to treat a wide range of conditions, many of them life-limiting diseases.
- Mainly because of the excellent results obtained with transplantation, demand for the therapy has gradually increased over the years, with a higher number of patients being placed on the waiting lists, while the number of donors and organs has not increased at the same rate. At present, it is not possible to meet the transplantation needs of the population, which are underestimated and are set to increase in the coming years.
- The degree of development of donation and transplantation activities varies greatly between countries, with the result that there is unequal access to transplantation services throughout the world. For a variety of reasons, deceased donation programmes have not been developed or fully consolidated in many countries, where transplantation activity, if any, mainly relies on live donation.
- As a result of shortage of organs for transplantation, many patients will never be placed on the waiting list. Many patients on waiting lists will deteriorate or die while waiting for an organ.
- Organ shortage, plus the extreme economic disparities and inequities in access to transplantation services throughout the world, are the main causes of trafficking in OTC and trafficking in human beings for the purpose of organ removal.
- Solving the shortage of organs for transplantation requires the development of an effective deceased donation programme. The effectiveness of such a programme mainly depends on organisational aspects. While there is no lack of potential deceased organ donors, there is an inability to identify them and successfully activate and develop the process of deceased donation.
- Living donation should be seen as being complementary to deceased donation. However, it has been the main or the only source of transplantable organs in many countries. Living donation involves risks for donors and cannot on its own meet the transplantation needs of a population.

B. Bioethics – the ethical framework for organ and tissue procurement

To close the gap between demand and supply of organs for transplantation, all manner of ideas are being floated on how to encourage people to give more organs when they die, optimise performance in the process of donation, enable more people to act as living donors and even find new sources of organs and tissues by rethinking organ procurement and the definition of who can be a deceased donor. These ideas were summarised in the previous section. In order for policy-makers to consider the merit of new options for encouraging people to donate OTC, it is necessary fully to understand the bioethical framework that has guided organ and tissue donation in nearly every part of the world since its inception in the 1950s.

It is also necessary to think hard about the most effective and fair way of distributing scarce organs, including who on the waiting lists should receive transplants first. Fairness is a crucial element in determining the supply of donated organs and tissues. If the public do not believe the allocation of organs and tissues is fair, they will be far less willing to donate their organs or tissues upon their death or as living donors. Trust and altruism require fairness as a basis for organ and tissue donation.

The existing bioethical framework for obtaining organs and tissues

The existing bioethical framework for obtaining organs and tissues is based on four key values – respect for individuals, autonomy, consent and altruism. The notion that organs or tissues can be removed for the purposes of transplantation, whether the individual concerned is alive or dead, without voluntary consent is one that has not been accepted except in highly unusual circumstances (i.e., unclaimed bodies at morgues in some countries). Individuals are recognised as having an interest in controlling their bodies in life and upon death. They are to be treated with dignity and not merely used to serve the health needs of others. So even though someone might well benefit from obtaining my liver or receiving bone marrow from my body, these organs and tissues ought not to be removed from me without my permission. To do so is to commit an assault upon a living person or to desecrate the body of a newly deceased person. Part of the notion of treating individuals with dignity is that they have control over what is done with their own bodies and their parts.

Another core element of the existing bioethical framework is that the body and its parts must not be made the subject of trade. The prohibition of slavery and of trafficking in persons for prostitution is based upon the ethical principle that human beings ought not to be bought and sold as objects, and transplantation has incorporated this view in the prohibition of trading in body parts for profit. In part, this is a bioethical view that rests upon the fundamental dignity of individuals. In part, it is a principle that reflects the huge dangers that would loom for human health and welfare if trade for profit in human body parts from the dead or the living were permitted. Altruism is the bioethical foundation as reflected in the use of the term "donation" for obtaining organs in a manner consistent with human dignity.

In order to obtain organs and tissues from the living, there is agreement that, from an ethical standpoint, it is necessary to have a legally competent individual who is fully informed and can make a voluntary, uncoerced choice about donation. In cases where organs and tissues are sought from the deceased, the notion of voluntary consent has been extended in many countries to the recognition of donor cards or, for those not wishing to donate, the recording of objections in

computer-based registries. While various policies about who is responsible for giving consent exist throughout the world, from a bioethical perspective, it is voluntary, informed consent that is crucial in making organ and tissue procurement ethical.

Proposals to increase the supply of organs must be weighed up very carefully against this existing bioethical framework which has long been effective in protecting the interests of prospective donors. Changes in the relevant values might well alienate the public who have grown used to the existing bioethical framework, major religious groups who have long supported it or healthcare workers, the majority of whom firmly believe that the current bioethical framework is the right one for governing organ, tissue and cell procurement for transplantation purposes.

Increasing the supply

A number of steps have been taken over the years in many countries to try to increase the supply of organs. An early measure was to pass laws permitting the use of organ donor cards that enabled families to consent to donating a deceased relative's organs.

Some countries began requiring hospitals to ask all patients' families about organ and tissue donation upon death. Most recently, some countries now require hospitals to honour a patient's donor card even when a family member opposes donation.

While these policies have been effective, the gap in supply has continued to increase. Some people now therefore argue for a shift away from reliance on voluntary altruism in organ donation towards either a paid market or presumed consent.

Organ markets

Two basic strategies have been proposed to provide incentives for people to sell their organs upon their death. One strategy is simply to permit organ sales by allowing individuals to broker contracts while alive with persons interested in buying at prices mutually agreed upon by both parties. At least in an underground sense, markets already exist on the Internet between potential live donors and people in need of organs.

The other strategy is a "regulated" market in which the government would act as the purchaser of organs – setting a fixed price and enforcing conditions of sale. Iran appears to have such a market in operation, although data on how it is specifically organised and how well it functions raise important ethical questions about the approach.[63] In 1998, with a transplantation programme based on related living donors which was unable to cope with the demand for kidney transplantation within the country, a model of unrelated living donation, involving payments but controlled by the government, was developed in Iran. It is the government itself which remunerates the "voluntary" donors and provides them with one year medical insurance and with social recognition for the act of donation. The model has been shown to attain its objectives: Iran is the only country in the world with no waiting list for kidney transplantation, the system produces excellent post-transplant outcomes and it has avoided the problem of transplant tourism by prohibiting transplantation to foreigners with organs from local donors. The supporters of this controlled organ trade state that it is the most suitable model in the particular context of the country, which might not be understandable from a western perspective. However, Iranians have themselves openly recognised the limitations of this system, including the common additional remuneration usually paid by the recipient to the unrelated living donor.

Both proposals have drawn heated ethical criticism. One criticism is that only the poor and desperate will want to sell their body parts. If you need money, you might sell your kidney to try and feed your family or to pay back a debt. This may be a "rational" decision, but that does not make it a matter of free, voluntary choice.

Watching your child go hungry when you have no job and a wealthy person waves a wad of money in your face is not exactly a scenario that inspires confidence in the "choice" made by those with few options but to sell body parts. Talk of individual rights and autonomy is hollow if those with no options must "choose" to sell their organs to purchase life's basic necessities. Choice requires information, options and some degree of freedom, as well as the ability to reason about risks without being blinded by the prospect of short-term gain.

It is hard to imagine many people in wealthy countries being eager to sell their organs either while alive or upon their death. In fact, even if compensation is relatively high, few will agree to sell. That has been the experience with markets in human eggs for research purposes and with paid surrogacy in the United States – prices have escalated, but there are still relatively few sellers.

Selling organs, even in a tightly regulated market, violates the existing bioethical framework of respect for individuals since the sale is clearly

63. Ghods AJ, Mahdavi M. Organ transplantation in Iran. Saudi J Kidney Dis Transpl 2007; 18: 648-655.

being driven by profit. In the case of living persons, it also violates the ethics of medicine itself. The core ethical norm of the medical profession is the principle, "Do no harm." The only way that removing an organ from someone seems morally defensible is if the donor chooses to undergo the harm of surgery solely to make money.

The creation of a market in body parts puts medicine in the position of removing body parts from people solely to abet those people's interest in securing compensation as well as to let middle-men profit.

Is this a role that the health professions can ethically countenance? In a market – even a regulated one – doctors and nurses still would be using their skills to help living people harm themselves solely for money. In a deceased market, they would risk making families and patients uncertain about the degree to which appropriate care was being offered and continued and whether a person might be worth more 'dead than alive'. The resulting distrust and loss of professional standards is a high price to pay for gambling on the hope that a market might secure more organs and tissues for those in need.

Presumed consent

There is another option for increasing organ supply that has been tried in countries such as Spain, Italy, Austria, Belgium and Singapore. These countries have passed laws establishing presumed consent. Under this system, the presumption is that a deceased person wishes to be an organ donor upon their death – basically an ethical default reflecting the desirability of donation. People who do not wish to be organ donors have to say so while alive by carrying a card indicating their objection or by registering their objection in a computerised registry or both. They may also tell their loved ones and rely on them to object should procurement present itself as an option.

What is important about this strategy from a bioethical perspective is that it is completely consistent with the existing bioethical framework governing organ and tissue procurement.

Respect for individuals and voluntary, altruistic consent remains the moral foundation for making organs available. The main ethical objection to presumed consent is fear of mistakes in the event of consent being presumed when, in fact, either the individual had failed to indicate their objection or the record of their objection had been lost.

Distributing organs: what is just and fair?

Rationing is unavoidable in organ transplantation, but the system for allocating organs must be just and fair. Justice requires some rule or policy which makes sure that the supply of donated organs is used wisely and in accordance with what donors and their families would wish. Fairness demands that like cases of need be treated alike and that the allocation system is transparent so that all individuals on waiting lists know why some are selected and some are not. The existing bioethical framework cannot function without public confidence and trust.

Transplant centres are the gatekeepers who decide who will or will not be accepted as transplant candidates. Their policies vary. Many non-medical values shape their decisions, and it can be argued that some centres invoke these values in ways that are not truly just. Among these considerations, many transplant centres will not accept people over 75 years of age. Some centres exclude patients with moderate mental retardation, HIV, a history of addiction or a criminal record.

Value judgments may also influence the process of matching deceased donor organs with patients on waiting lists. For example, in the United States, the UNOS bears this responsibility. At present, its overriding concerns are to match donors and recipients by blood type, tissue type and organ size. Some weight is also given to the urgency or need for a transplant as reflected by time on the waiting list and the person's physical condition. There have been some moves in recent years to steer organs toward those who are not seriously ill so as to maximise the chances for successful transplantation. UNOS used to allocate organs locally, but recently it has moved to more regionalised distribution arrangements in the interest of fairness.

It is crucial from a bioethical perspective that the criteria used to determine who receives a transplant are transparent, open to public debate and consistently applied. If not, confidence in transplantation would be lost with a devastating impact on organ and tissue donation.

This section on the ethical framework for organ and tissue procurement may be summarised in the following key points:

- The existing bioethical framework for obtaining OTC for transplantation is based on four key values – respect for individuals, autonomy, consent and altruism. Proposals to increase the supply of organs must be weighed up very carefully against this existing bioethical framework.
- Organ markets as a solution for increasing organ supply do not respect this bioethical framework. Free, voluntary choices cannot be made in the case of living donors when purchase is the reason behind donation. Commerce in donation and transplantation would shake the basic foundations of medicine, undermining a system based on altruism that already works in many countries.
- It is crucial from a bioethical perspective that the criteria used to determine who receives a transplant are transparent, open to public debate and consistently applied. Otherwise, loss of confidence in transplantation would have a devastating impact on organ and tissue donation.

C. Existing international standards

World Health Organization and World Health Assembly

The World Health Assembly first expressed its concern regarding trafficking in organs and the need for global standards for transplantation in *Resolution WHA40.13* adopted by the 40th World Health Assembly in May 1987 and in *Resolution WHA42.5 on preventing the purchase and sale of human organs* adopted by the 42nd World Health Assembly in May 1989. In response to these resolutions, the World Health Assembly in 1991 adopted *Resolution WHA44.25* endorsing a set of *Guiding Principles on Human Organ Transplantation*. These Guiding Principles – whose emphases include voluntary donation, non-commercialisation, genetic relation of recipients to donors and a preference for deceased over living donors as sources – have considerably influenced professional codes, legislation and policies.

In its report *"Human organ and tissue transplantation"* (EB112/5) of 2 May 2003, the World Health Organization (WHO) refers to medical and legal developments. While still favouring deceased donors, the report emphasises that improvements in immunosuppression reduce the need for living donors to be genetically related to the recipient, which means that still more attention must be paid to ensuring that consent is given on an informed and voluntary basis. Despite advances in safety measures for human organ and tissue transplantation, donors and transplant recipients still face several risks which call for safety and quality measures. Lastly, the report underlines that proposals to offer financial incentives for the provision of human body material in the hope of increasing access to transplantation need to be carefully scrutinised.

In May 2003, the Executive Board of the WHO agreed at its 112th session to set up a group of experts to prepare a report regarding organ and tissue transplantation, including xenotransplantation.

In October 2003, the First Global Consultation on "Ethics, access and safety in tissue and organ transplantation: Issues of global concern" took place in Madrid. At this meeting, issues regarding ethics, access and safety in transplantations were analysed. Because of changes in practices and attitudes regarding organ and tissue transplantation, in May 2004, the 57th World Health Assembly in Resolution *WHA57.18 on Human Organ and Tissue Transplantation* – based on the findings in the above-mentioned report – requested that the Director-General, inter alia, continue examining and collecting global data in order to update the Guiding Principles on Human Organ Transplantation. Furthermore, it called for enhanced co-operation, the setting up of ethics groups, extension of the use of living kidney donations when possible, in addition to donations from deceased donors, and the adoption of measures to protect the poorest and vulnerable groups from "transplant tourism" and the sale of tissues and organs, including by giving attention to international trafficking in human tissues and organs.

Resolution *WHA57.18 on Human Organ and Tissue Transplantation* was followed by a number of activities and discussions, including the Second Global Consultation on Human Transplantation: Towards a Common Global Attitude to Transplantation, held in Geneva from 28 to 30 March 2007. At this meeting, an update of the 1991 Guiding Principles was also strongly favoured by participants. The Global Observatory on Donation and Transplantation[64] was also developed by the Spanish National Transplant Organisation (ONT) in collaboration with WHO in response to some of the requests made in *WHA57.18*, for instance collecting global data on practices and ensuring transparency of the systems in place.

At its 123rd session on 26 May 2008, the WHO Executive Board took note of the *revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, and it is anticipated that a resolution of the next Executive Board session will lead to these revised Guiding Principles being presented to the World Health Assembly in 2010.

64. See note 13, page 19.

Council of Europe

Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances

The Council of Europe started activities related to transplantation at an early date: as far back as 1978, the Committee of Ministers adopted *Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances,* which deals with substances from living and deceased persons, setting out certain principles for both. It is important to note that the basic principles are already laid down in this document:

- The issue of consent in the case of living donors is dealt with prominently. Article 2 provides that the donor and, in the case of a minor or otherwise legally incapacitated person, his or her legal representative must be given appropriate information before the removal about the possible consequences of the removal, in particular the medical, social and psychological ones, as well as about the importance of the donation for the recipient. Article 3 lays down the principle that the removal must not be effected without the consent of the donor and that this consent must be given freely.
- The second major issue is dealt with in Article 9 for substances from living donors and in Article 14 for those from deceased persons: no substance (organ) may be offered for profit. For living donors, the resolution nonetheless provides that loss of earnings and any expenses caused by the removal or preceding examinations may be refunded and that the (potential) donor must be compensated, independently of any possible medical responsibility, for any damage sustained as a result of a removal procedure or preceding examination, under a social security or other insurance scheme. These basic rules can now be found in all modern legal instruments and recommendations and their substance is undisputed. However, several questions seem to remain open concerning their meaning, especially the range of expenses that are excluded as regards the term "non-profit", as became evident, *inter alia*, during the discussion of the *draft EU framework decision concerning prevention and control of trafficking in human organs and tissues* (see below, page 70).
- In addition, respect for the donor's and recipient's anonymity except in cases of close personal or family relationships between the two was already clearly defined (Article 2 (2) regarding organs from living donors and Article 13 regarding organs from deceased donors).

The main principles for transplantations were therefore already set out in this resolution, which must be seen as one of the first international instruments ever to deal with the topic. However, the resolution is not binding and does not include any provisions on sanctions.

The conclusions of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987)

The *conclusions of the 3rd Conference of European Health Ministers* (Paris, 16-17 November 1987) on the subject of "Organ transplantation" set out agreed guidelines which were based on Resolution (78) 29 but further elaborated them and formed a basis for future work and co-operation within the member states of the Council of Europe. It was unanimously agreed that there was a need to protect individual rights and freedoms, to avoid the commercialisation of organ procurement, exchange and transplantation activities, to develop an information policy on the significance of organ transplantation and to promote European co-operation.[65] The text dealt with issues regarding the removal of organs (including skin and bone marrow, but excluding testicles, ovaries, embryos, ova, sperm and blood) from deceased and living donors, establishing guidelines and restrictions for the procedure to be applied and the cases in which such removals should take place.

The need for free, legal consent was expressly reiterated, along with the principle that no removal should be effected from a legally incapacitated person.[66]

The second main aspect, namely the principle of non-commercialisation of human organs, was also reiterated: Chapter II, paragraph 16, of the final declaration states that a human organ must not be offered for profit, but that this does not prevent the compensation of living donors for loss of earnings and any expenses caused by the removal or preceding examination. The Council of Europe thereby stressed this aspect for a second time, showing clear political will, but still in a non-binding format.

Chapter III of the conclusions establishes clear criteria for the use of human organs, i.e. rational use of organs where there is the maximum prospect of success, solely based on medical criteria. The necessary controls to ensure that both removals and transplantations take place in officially recognised institutions with adequately trained and experienced staff and equipment are mentioned in Chapter IV.

65. See: Paragraph 6 of the conclusions of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987).
66. Conclusions of the 3rd Conference of European Health Ministers (Paris, 16-17 November 1987), paragraphs I.B. (9) and (10).

Chapter V covers information policy to inform the public of the significance of organ transplantations in saving lives and respective organisational measures. As early as 1987, the importance of organisational measures for the promotion of European co-operation was recognised. Chapter VI recommended that in order to avoid wastage of organs resulting from inability to find the right recipient, organs which, on the basis of medical criteria, cannot be used in the donor's country should be made available on the basis of the same criteria to patients in other countries, preferably through European exchange organisations on a strictly non-commercial basis.

In short, the *conclusions of the 1987 3rd Conference of European Health Ministers* already included most of the elements of modern recommendations and standards and served – together with *Resolution (78)* – as the basis for the leading international instrument in this field, the *1997 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS No. 164)*. As such, the declaration was a strong political statement, but in a non-binding format.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (CETS No. 164)

After various activities within the Council of Europe, it became apparent that greater efforts to harmonise existing standards regarding the application of biology and medicine were needed. The European Ministers of Justice adopted *Resolution No. 3 on bioethics* at their 17th Conference (Istanbul, 5-7 June 1990), recommending that the Committee of Ministers instruct the ad hoc Committee of Experts on Bioethics (CAHBI) to examine the possibility of preparing a framework convention "setting out common general standards for the protection of the human person in the context of the development of the biomedical sciences". In June 1991, the Parliamentary Assembly, in *Recommendation 1160*, supported the idea of a framework convention comprising a main text with general principles and additional protocols on specific aspects. In September 1991, the Committee of Ministers instructed the CAHBI to prepare "a framework Convention, open to non-member states, setting out common general standards for the protection of the human person in the context of the biomedical sciences and Protocols to this Convention, relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings".

In July 1994, an initial version of the draft convention was subjected to public consultation and submitted to the Parliamentary Assembly. In the light of the Assembly's opinion and of several other positions adopted, a final draft was drawn up by the Steering Committee on Bioethics (the successor to the CAHBI) on 7 June 1996 and again submitted to the Parliamentary Assembly. Finally, the convention (CETS No. 164) was adopted by the Committee of Ministers on 19 November 1996 and opened for signature on 4 April 1997 in Oviedo (Spain). It entered into force on 1 December 1999 and had been signed by 34 states and ratified by 22 as at December 2008.

The **aim** of the *Convention on Human Rights and Biomedicine* is to guarantee everyone's integrity, rights and fundamental freedoms with regard to the application of biology and medicine and protect the dignity and identity of human beings in this sphere (Article 1), thereby putting the human being before the interest of society or science (Article 2) and, moreover, before all other considerations.

With regard to trafficking in organs and the main issues related to it, the following should be noted: Chapter II of the convention deals with the general **issue of consent**. Article 5 lays down the general rule that an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it and that he or she may freely withdraw his or her consent at any time. This article affirms the already well-established principle of patients' autonomy, meaning that no person should undergo any intervention without his or her consent. An individual must therefore be able freely to give consent to any intervention involving their person and to refuse it at any time. But consent alone is not enough; it needs to be **informed** and has to be **given freely**. According to Article 5 (2), the person must therefore be given appropriate information beforehand as to the purpose and nature of the intervention as well as its consequences and risks.

Informed consent: Naturally, such information should be given by the responsible healthcare professionals, as it is they who know the details of the planned intervention and of possible alternatives, as well as the characteristics of the patient on whom the intervention is going to be performed (age, sex, specific health risks, etc.) and which can influence its outcome. According to the explanatory report on the convention, Article 5 (2) mentions only the most important aspects of the information which should precede the intervention, but should not be seen as an exhaustive list, i.e. informed consent may imply additional elements, depending on the circumstances.

As is the case for any other information, it must be sufficiently clear and suitably worded for the patient to understand. He or she must be put in a position to evaluate the need for and usefulness of the intervention and the methods to be applied, as well as the

risks. This means that the information should not only be provided in a language the patient understands, but also that the terms used should be understandable.

Article 5 does not require a special form for the consent; it can be express (either verbal or written) or implied. However, for invasive interventions, express consent may be required and in the case of the removal of body parts for transplantation purposes the patient's express, specific consent must be obtained (Article 19).

Free consent: Freedom of consent implies that it may be given and withdrawn at any time and that the decision has to be respected; no pressure of whatever kind may be used and nobody may ignore this requirement. The patient is entitled to information, but, as provided for in Article 10 (2), the wishes of individuals not to be informed must be observed. However, Article 10 (3) limits this insofar as in exceptional cases restrictions may be placed by law on the exercise of this right in the interests of the patient.

Basically, the patient's exercising of the aforementioned right is not regarded as an impediment to the validity of his or her consent to an intervention; e.g. he or she can validly consent to the removal of a cyst despite not wishing to know its nature,[67] but there are certain circumstances where it could also be appropriate to inform an individual that he or she has a particular condition when there is a risk not only to that person but also to others. The right also has to be qualified if there is a major risk for the person him- or herself, e.g. before invasive interventions like the removal of organs, where the risk for the donor is so high and the consequences so far-reaching that valid consent is not possible without the donor receiving certain information in order to give such consent.

67. Explanatory report on the Convention on Human Rights and Biomedicine, paragraph 67.

Specific cases: Article 6 of the *Convention on Human Rights and Biomedicine* takes account of the fact that interventions may also have to be carried out on persons who do not have the capacity to give full and valid consent. According to Article 6 (1), an intervention may only be carried out on such a person for his or her direct benefit. Deviation from this rule is possible in only two cases: medical research and the removal of regenerative tissue (Articles 17 and 20).

Where, according to law, a minor (Article 6 (2)) or an adult – because of a mental disability, a disease or for similar reasons[68] (Article 6 (3)) – do not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of their representative or an authority or a person or body provided for by law. Nonetheless, the opinion of the minor must be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity and the adult unable to consent must as far as possible take part in the authorisation procedure.

This means that in certain situations which take account of the nature and seriousness of the intervention, as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. This could even lead to the conclusion that the consent of a minor should be necessary, or at least sufficient for some interventions.[69] Taking into account the nature and seriousness of removal of organs, it can therefore be inferred (in line with Article 12 of the *United Nations Convention on the Rights of the Child*) that, depending on the child's age, maturity and ability to understand, his or her consent may be necessary.

68. The term "similar reasons" refers to such situations as accidents or states of coma, for example, where the patient is unable to formulate his or her wishes or to communicate them (Explanatory report on the Convention on Human Rights and Biomedicine, paragraph 43).

69. Explanatory report on the Convention on Human Rights and Biomedicine, paragraph 45.

Organ and tissue removal from living donors for transplantation purposes: A separate chapter of the *Convention on Human Rights and Biomedicine* deals with organ and tissue removal from living donors for transplantation purposes (Chapter VI). As a general rule, Article 19 provides that removal of organs or tissue from a living person for transplantation purposes may be carried out **solely for the therapeutic benefit of the recipient** and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

In line with the previous work of the Council of Europe in this field, the purpose of this chapter is to establish a framework to protect living donors in the context of organ or tissue removal. Underlining the dignity and human rights of individuals, it is made clear that the first requirement for the removal of organs or tissues from a living person for transplantation purposes is the therapeutic benefit of the recipient. Of course, the recipient's needs have to be known before the removal of the organ, as it would be a violation of basic human rights principles if an organ were to be removed without the immediate and urgent need of a specific patient and thereafter maybe even be wasted because of inability to find a matching recipient.

The second principle is that the **use of organs or tissues from deceased donors should be preferred to those from living donors** whenever possible because an intervention always bears a certain risk for the patient. And the last condition in the case of living donors is that the **therapeutic benefit for the recipient cannot be achieved by alternative therapeutic methods of comparable effectiveness**.

In view of all these requirements, it can be seen that the *Convention on Human Rights and Biomedicine* care-

fully takes into account the human rights of both donors and recipients: it balances patients' need for transplantations with a restriction on the use of organ and tissue removals from living donors because of the risk involved; there can be no justification for resorting to living donors if there are other methods for bringing the same benefit to the recipient. The transplant must therefore be necessary in the sense that there is no other solution with similar results. In this respect, dialysis treatment is not considered to provide results in terms of the patient's quality of life comparable with those obtained by a kidney transplant.[70]

Regarding consent, Article 19 (2) makes the general rule of Article 5 stricter by stating that, in the case of organ removal, the necessary **consent** must have been given **expressly and specifically** either in written form or before an official body, e.g. a court or a notary. This is because the invasive nature of this intervention entails more requirements for valid consent because of the risks it involves for the person.

Article 20 (1) clearly prohibits organ or tissue removal being carried out on a person who does not have the capacity to consent under Article 5.
Article 20 (2) further specifies that exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised, **provided that certain conditions are met**: the first condition is that – within reasonable limits – no compatible donor is available who is able to consent. Additionally, in the absence of the donation, the recipient's life must be in danger, and the risks to the donor must be acceptable. Also, the recipient must be a brother or sister of the donor to avoid efforts being made to find a donor at any price (such as donors at a distant level of kinship where the chances of tissue incompatibility are much higher). Moreover, the authorisation of the representative of the person unable to consent must be given – in accordance with Article 6 (2) and (3) – specifically and in writing, in accordance with the law and with the approval of the competent body. Of course, this approval must be given before the removal can be carried out. Lastly, the removal may not be carried out if the potential donor objects; such an objection must be observed in all circumstances.

Chapter VII sets out a basic principle which has now achieved worldwide recognition, namely **the prohibition of financial gain,** and also covers the issue of **disposal of parts of the human body**. Article 21 is the most prominent provision of the *Convention on Human Rights and Biomedicine*: "The human body and its parts shall not, as such, give rise to financial gain". It directly applies the principle of human dignity provided for in Article 1. According to Article 21, organs and tissues must not be traded or give rise to financial gain – either for the donor or for a third party. However, the provision does not prevent a donor from receiving compensation which, while not constituting remuneration, compensates the individual for expenses incurred or loss of income.

According to Article 22, when in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures (Article 5). Depending on the circumstances (nature of the use of the removed parts, collection of sensitive data about individuals, etc), the information and consent requirements may vary. Article 22 is no exception to the principle in Article 19 that removal of organs for transplantation purposes may be carried out only for the benefit of the recipient. But it does provide for the possibility that, in cases where the organ appears not to be suitable for transplantation purposes, it may exceptionally be used for research.

According to Article 23, parties to the convention must provide judicial protection to prevent or stop unlawful infringements of the rights and principles set out in the convention.
Article 24 provides that persons suffering undue damage resulting from an intervention are entitled to fair compensation according to the conditions and procedures prescribed by law. And lastly, according to Article 25, parties must provide for appropriate sanctions to be applied in the case of infringement of the convention's provisions.

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186)

With the *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* (CETS No. 186; hereafter: the Additional Protocol), the Council of Europe seeks to ensure the protection of individuals in the area of transplantations.

On the basis of *Recommendation 1160 (1991)* and the Committee of Ministers' instructions to the ad hoc Committee of Experts on Bioethics (CAHBI) to prepare protocols to the *Convention on Human Rights and Biomedicine*, "relating to, in a preliminary phase: organ transplants and the use of substances of human origin; medical research on human beings", the CAHBI in November 1991 appointed a Working Party on Organ Transplantation to prepare the draft protocol. As the work on the convention itself took precedence, the work on the protocol was postponed until January 1997. In June 1996, the Steering Committee on Bioethics (CDBI) extended the Working Party's terms of reference to examine the draft protocol in the light

70. Explanatory report on the Convention on Human Rights and Biomedicine, paragraph 119.

of the text of the convention. After a consultation process, the Additional Protocol was adopted by the Committee of Ministers on 8 November 2001.

The *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* (CETS No. 186) was opened for signature in Strasbourg on 24 January 2002. States which signed the *Convention on Human Rights and Biomedicine* can also become signatories to this protocol. It entered into force on 1 May 2006. As at December 2008, 20 states had signed and eight had ratified the protocol.

The *Additional Protocol* aims to protect the dignity and identity of individuals and the respect for their integrity and other rights and fundamental freedoms regarding transplantation of organs and tissues of human origin (Article 1) and cells (including haematopoietic stem cells; Article 2 (2)), thereby excluding issues of xenotransplantation. Under Article 2 (3), reproductive organs and tissues (a), embryonic or foetal organs and tissues (b) and blood and blood derivatives (c) are also excluded from its scope.

It furthermore only concerns the removal of organs or tissues from someone who has been born and the implantation of that organ or tissue, for therapeutic purposes, into someone else who has been born, including procedures of investigation, preparation of donors and recipients and preservation and storage of organs and tissues (Article 2 (1) and (4)).

In line with the *Convention on Human Rights and Biomedicine* and numerous recommendations of the Council of Europe and the World Health Organization, Article 3 (1) requires Parties to the *Additional Protocol* to provide **equitable** access to transplantation services for patients. The *Additional Protocol* leaves it to states to decide whether to fulfil this obligation through national or international organisations, which must ensure the rights and freedoms of (potential) donors and recipients. Because of the shortage of organs, they must be allocated in such a way as to maximise the benefit, which means that transplantation services must be equally accessible on a non-discriminatory basis to any person within the jurisdiction of a state.

Article 8 is closely linked with this provision. It requires states to inform health professionals and the public about the need for organs and tissues and the conditions for removal and implantation, including issues of consent and authorisation, especially regarding removal from deceased persons. This is important for raising awareness and promoting organ and tissue donations, while making the system known and acceptable to the public and establishing trust in it.

Article 3 (2) provides that organs and tissues may be allocated only to patients on waiting lists, in conformity with transparent, objective and duly justified rules according to medical criteria. National systems may establish different criteria for transplantation of various organs and tissues, but they must all follow medical criteria. According to the explanatory report, this should be understood in the broadest sense, "in the light of the relevant professional standards and obligations, extending to any circumstance capable of influencing the state of the patient's health, the quality of the transplanted material or the outcome of the transplant. Examples would be the compatibility of the organ or tissue with the recipient, medical urgency, the transportation time for the organ, the time spent on the waiting list, particular difficulty in finding an appropriate organ for certain patients (...) and the expected transplantation result."[71] In short, the criteria must be objective and patient-oriented and it goes without saying that they must be determined in advance and be transparent in order to exclude malpractice. This also means that, apart from these criteria, the person or body responsible for determining them must be clearly known and must be accountable for the decisions taken. Moreover, patients may only be registered on one waiting list so that all patients have equal chances.

For international organ exchanges, justified and effective distribution of organs according to the **solidarity principle** within and among the participating countries is required (Article 3 (3)). The **traceability** of organs and tissues must be ensured (Article 3 (4)), which means that it must be possible to track organs and tissues from the donor to the recipient(s) and back. This is not only necessary for health reasons (e.g. in case of transmissible diseases) but also in order to evaluate the use of transplanted material and prevent trafficking in organs and tissues.

Article 4 reiterates the basic rule already laid down in Article 4 of the *Convention on Human Rights and Biomedicine* that all interventions in the field of transplantation must be carried out in accordance with relevant professional obligations and standards. First of all, these require that the persons involved act in the patient's best interest and that the potential benefit to the recipient outweighs the risks to the donor. In addition, the existence of a clear medical indication for transplantation must be verified and all professional and ethical codes of conduct must be complied with. Among other things, different doctors need to take care of the donor and the recipient so as to guarantee the best treatment for both patients and avoid conflicts of interest.

Closely linked with these principles are the requirements to provide medical follow-up to the donor and the recipient after the transplantation (Article 7) and that all professionals involved must take the necessary

71. Explanatory report on the Additional Protocol (CETS No. 186), paragraph 37.

measures to minimise the risks of transmission of disease and to avoid actions which might affect the suitability of organs or tissues for transplantation.

Article 5 reiterates the recipient's right to comprehensive information prior to the intervention in a language he or she can understand so that he or she can give informed consent to the transplantation.

Chapter III deals with **organ and tissue removals from living persons**.

Article 9 reiterates the content of Article 19 of the *Convention on Human Rights and Biomedicine*, i.e. that organs or tissues may be removed from living persons solely for the recipient's therapeutic benefit, where there are no suitable organs or tissues available from deceased persons and where there is no alternative therapeutic method of comparable effectiveness.

Article 10 restricts **potential living organ donors** to those having a close relationship with the recipient as defined by law or under the conditions defined by law and with the approval of an independent body (e.g. an ethics committee). Some national laws do not define close relationships, while others do – and in various degrees; such relationships may include relatives (of various degrees), spouses and even close friends. If such close relationships do not exist, transplantation may still be proposed, but an independent body must be involved in the procedure to prevent organ trafficking.

Article 11 protects the potential donor by keeping the risks for him or her to a minimum. Article 11 (1) requires appropriate medical investigations and interventions (examinations, tests, medical acts, etc) to be carried out before any organ or tissue removal takes place so as to evaluate and reduce physical risks to the health of the donor. Article 11 (2) provides that the life and health of the potential donor must take precedence, i.e. no removal is to be carried out if there is a serious threat to them. In this sense, it is a counterbalance to Article 4 because clearly there is always a certain risk connected with donations, which must be outweighed by the benefit to the recipient. However, if that risk seriously endangers the donor, the donation procedure has to be stopped. This is also one more argument in support of the requirement that different medical teams should take care of the potential donor and the recipient, as different aspects have precedence for the two individuals and could otherwise lead to a clash of interests.

The next articles are closely linked with one another and the issue of **informed and free consent**. According to Article 12 of the *Additional Protocol*, the donor must be given appropriate information beforehand regarding the purpose and nature of the removal, its consequences and risks. This means that the information has to be comprehensive and in a form the potential donor understands (including both the language and also its level, e.g. in the case of minor donors). The same right applies to a person or body in charge of approving such an intervention if the donor is unable to consent.

Article 12 (2) further specifies that the donor must also be informed of the legal rights and safeguards, inter alia to have access to independent advice by experienced health officials not involved in the whole procedure. Consequently, an additional requirement applies: the potential donor must be given enough time for his or her decision, especially since the decision is one with far-reaching impacts. Written information which can be studied by the donor and can serve as a basis for information and questions is helpful and should be handed out.

Article 13 of the *Additional Protocol* is based on Articles 5 and 19 (2) of the *Convention on Human Rights and Biomedicine*. A donor must give free, informed and specific consent to the removal, either in written form or before an official body, and must be able to withdraw it at any time (see Chapter II.C.1.c.). However, unlike the act of giving consent, no specific formalities apply for its withdrawal. This is an important measure to protect the donor's human rights and the voluntary nature of the donation. The possibility of withdrawing consent applies to the removal, and only the removal. The provision does not tackle the issue of what should happen if the donor suddenly withdraws consent to the planned implantation. Such issues have to be addressed by national law. To avoid psychological problems or keep them to a minimum, to avoid undue pressure to donate and also to enable donors to cope with potential rejection by the potential recipient of the organ, psychological assistance must be regarded as part of the information (Article 12) which is the basis for informed consent.

Article 14 of the *Additional Protocol* on the protection of persons not able to consent to organ or tissue removal repeats Article 20 of the *Convention on Human Rights and Biomedicine*.

Article 15 limits the **requirements for such cell removals from living donors which involve a minimal risk and burden for the donor**. It allows states not to apply two of the strict requirements, i.e. limiting the recipient to the donor's brother or sister and that the donation should have the potential to be life-saving. However, the other conditions set out in Article 14 remain applicable in any case.

Chapter IV of the *Additional Protocol* deals with issues regarding **organ and tissue removal from deceased persons**. Article 16 is designed to safeguard patients and public trust in transplantations, while at the same time preventing unethical behaviour by requiring that a person must first be certified dead in accordance with the law before any removal from his or her body takes place and that the doctors certifying brain death must not be directly involved in the removal of organs or tissues from that person,

in any subsequent transplantation or have any responsibility for the care of the potential recipient, so as to avoid any conflict of interests. The system for establishing brain death is left to states.

According to Article 17, no removal may take place until the consent or authorisation required by law has been obtained, in particular no removal is to be carried out if the deceased has objected to it. This provision requires states to have a **legally recognised system regulating the conditions for the authorisation of the removal of organs and tissues from deceased persons**, but leaves it to them to decide upon its nature. It therefore leaves scope for "opt-in" and "opt-out" solutions (see chapter XXX). However, Article 17 clearly indicates that the wishes of the deceased persons have to be respected and should be ascertained. For example, in several states there are official registers for recording consent to donations or objections to such; there are also registers of last wills. If the will of the deceased is not known, there must be a law indicating the procedure to be applied. The arrangements are also left to states and they may either allow the removal if no objection is known or provide for consultation of relatives and friends to establish the wishes of the deceased. Unless national law provides otherwise, however, it is the will of the deceased person only – and not of his or her relatives – that is relevant. If a person dies in a country in which he or she is not resident, every effort should be made to ascertain the wishes of the deceased.

Article 18 extends the right of integrity of the human body to deceased persons in stating that the corpse must be treated with respect and all reasonable measures be taken to restore its appearance. Article 19 calls on states to take all appropriate measures to **promote the donation of organs and tissues**, which in any case should involve informing health professionals and the public, setting up transplant systems and providing legal frameworks for consent and authorisation.

Chapter V of the *Additional Protocol* deals with the particular circumstance that organs or tissues are removed for purposes other than donation for implantation but are donated at a later stage. It requires the person from whom the organ or tissue is removed to be informed of the consequences of the implantation into another person (examination, tests, recording of data for traceability, information on risks, etc) and his or her consent (or that of an authorised person in the case of individuals who cannot legally consent) to implantation to be obtained. All the provisions of the protocol, except those in Chapters III and IV, are applicable.

Chapter VI on the **prohibition of financial gain** further elaborates the general principle laid down in Article 21 of the *Convention on Human Rights and Biomedicine*. It is a basic and recognised principle that the human body and its parts must not give rise to financial gain or comparable advantages. Article 21 (1) of the *Additional Protocol* draws a clear line between this prohibition and **payments whose purpose is not financial gain** but, on the contrary, the prevention of financial disadvantages. In particular, three types of payments are allowed:

- The first indent allows living donors to receive compensation for loss of earnings or other justifiable expenses caused by the removal or related examinations. This is an important measure, as the intrusive nature of the intervention means lengthy periods of sick leave are likely and may result in economic disadvantages for the donor.
- The second indent allows hospitals and staff to receive payment of **justifiable** fees for **legitimate** medical or related technical services rendered in connection with the transplantation (examinations, intervention, transport, storage, etc.), but no more and especially not in terms of their making financial gains from such transactions or, indeed, illegitimate ones.
- The last indent allows compensation for undue damage resulting from the removal of organs or tissues which is not a normal consequence of transplantations. It is closely linked to Article 25. Article 21 (2) prohibits advertising the need for, or availability of, organs and tissues with a view to offering or seeking financial gain or comparable advantage.

Article 22 of the *Additional Protocol* expressly sets out the **prohibition of organ and tissue trafficking**, which are key examples of making financial gains from the human body or its parts. Moreover, organ and tissue trafficking infringe human rights, exploit vulnerable persons and undermine public trust in the official transplant system.

Article 23 lays down the **principle of confidentiality of data** relating to donors and recipients; the data must be handled in accordance with the provisions on data protection. However, this must not prevent the traceability of the organ or tissue or prevent the medical teams involved in the transplantation process obtaining the necessary medical information; otherwise, proper medical interventions in the transplantations and any subsequent diseases would not be possible.

According to Article 24, unlawful infringements of rights or principles set out in the protocol must be stopped at short notice by appropriate judicial means. Persons suffering undue damage resulting from transplantation procedures are entitled to fair **compensation** in accordance with states' legal conditions and procedures (Article 25), which are not defined by the protocol. As each transplantation involves some damage, Article 25 is limited to undue damage resulting from transplantation. Particular attention should be paid to

damage affecting (potential) living donors, as they consent to organ removal for altruistic reasons.

In the case of infringements of provisions in the protocol, states must provide appropriate **sanctions** according to Article 26. While leaving it to states to determine which form they should take, the text clearly indicates that the sanctions provided for must take into account the seriousness of the offences and their consequences for individuals and society.

Article 27 highlights the importance of **co-operation** between the parties, not only with regard to information exchange, but also through rapid and safe transportation of organs and tissues through their territory in order not to waste organs or tissues if suitable matches are found in other countries. It is therefore recommendable to enter into regional or international transplantation programmes.

Lastly, Article 28 of the *Additional Protocol* states that the aforementioned provisions are to be regarded as additional articles to the *Convention on Human Rights and Biomedicine* and that the convention's provisions apply accordingly.

Recommendations of the Council of Europe Committee of Ministers

In addition to the *Convention on Human Rights and Biomedicine* and its *Additional Protocol*, a wide range of recommendations of the Committee of Ministers to member states exist. Many of these deal with organisational and technical issues in the field. The main ones are listed below:

- Recommendation No. R (94) 1 on human tissue banks,
- Recommendation No. R (97) 15 on Xenotransplantation,
- Recommendation No. R (97) 16 on liver transplantation from living related donors,
- Recommendation Rec (2001) 4 on the prevention of the possible transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood transfusion,
- Recommendation Rec (2001) 5 on the management of organ transplant waiting lists and waiting times,
- Recommendation Rec (2003) 10 on xenotransplantation,
- Recommendation Rec (2003) 12 on organ donor registers,
- Recommendation Rec (2004) 7 on organ trafficking,
- Recommendation Rec (2004) 8 on autologous cord blood banks,
- Recommendation Rec (2004) 19 on criteria for the authorisation of organ transplantation facilities,
- Recommendation Rec (2005) 11 on the role and training of professionals responsible for organ donation (transplant "donor co-ordinators"),
- Recommendation Rec (2006) 15 on the background, functions and responsibilities of a National Transplant Organisation (NTO),
- Recommendation Rec (2006) 16 on quality improvement programmes for organ donation,
- Resolution CM/Res (2008) 4 on adult-to-adult living donor liver transplantation,
- Resolution CM/Res (2008) 5 on donor responsibility and on limitation to donation of blood and blood components, and
- Resolution CM/Res (2008) 6 on transplantation of kidneys from living donors who are not genetically related to the recipient.

Both *Resolutions CM/Res (2008) 4* and *CM/Res (2008) 6* are linked to the issue of trafficking in organs and point out that there is a need to protect individual rights and freedoms and to prevent the commercialisation of parts of the human body involved in organ procurement, exchange and allocation activities. They also acknowledge the scarcity of organs for transplantations and the fact that **organ transplantation is a well-established, life-saving and effective treatment and may be the only treatment available for some forms of end-stage organ failure**. They therefore state that organ removals from living donors may be envisaged when suitable organs from deceased donors are not available, provided that all safeguards are implemented in order to guarantee the freedom and safety of the donor and a successful transplant in the recipient, and stress that no organ removal may be carried out on a person who does not have the capacity to consent.

European Union

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004)

This directive recognised the fact that the use of organs to some extent raises the same issues as the use of tissues and cells, but nevertheless decided that the two subjects should not be covered by the same instrument because of the differences.[72] It does not therefore cover human organs, blood or blood products.

Even though human organs were not included in substantive terms, the directive nonetheless stressed two important points which should be mentioned:

- the need to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme "we

72. Directive 2004/23/EC, Recital 9.

are all potential donors" in order to help European citizens to decide to become donors during their lifetime and let their families or legal representatives know their wishes;[73] and

- the provision in Article 12 (2) that member states must take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions and include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage.

Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ L 38/40, 9.2.2006)

Commission Directive 2006/17/EC indicates that the risk of disease transmission and other potential adverse effects in recipients can be reduced by careful donor selection, testing of each donation and the application of special procedures for procuring tissues and cells. Alongside several provisions implementing certain technical requirements for the donation, procurement and testing of human tissues and cells, the directive includes four annexes covering selection criteria and laboratory tests for donors, as well as donation and procurement procedures and reception procedures.[74]

EU Charter of Fundamental Rights

Article 3 of the European Union's Charter of Fundamental Rights declares the right to the integrity of the person and provides that everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, this includes the free and informed consent of the person concerned, according to the procedures laid down by law, and the prohibition on making the human body and its parts as such a source of financial gain.

The question of the legal status of the Charter has been the focus of debate ever since it was drawn up. Full legal status would be obtained through its incorporation in the Treaty establishing a Constitution for Europe. This treaty was signed on 29 October 2004 but has still not been ratified by all EU member states, which is the requirement for its entry into force.

Communication from the Commission to the European Parliament and the Council on "Organ Donation and Transplantation: Policy Actions at EU level" (COM (2007) 275 final)

In May 2007, the European Commission adopted a Communication on Organ Donation and Transplantation in which three priority areas of action were identified: improving the quality and safety of organs, increasing organ availability and making transplantation systems more efficient and accessible. Two different actions were suggested: an action plan for strengthened co-ordination between member states on organ donation and transplantation and an EU directive on quality and safety of human organs (see below, page 43 *ff.*).

Council Conclusions on Organ Donation and Transplantation

On 6 December 2007, the Health Council adopted conclusions[75] in line with the above Commission Communication. The text invites member states to promote and enhance the performance of transplantation systems, to collect information on transplant medicine that would be helpful for designing and monitoring efficient policies and to exchange best practices and experience on organ donation and transplantation. The European Commission is invited to continue its work under the proposed action plan aimed at increasing the availability of donor organs and, in consultation with the member states, to continue its examination of the need for an EU framework on quality and safety for human organs taking into consideration the specificities of organ transplantation and the work carried out by the Council of Europe and, lastly, to co-ordinate, promote and strengthen the co-operation between the member states on organ donation and transplantation on the basis of agreed objectives and priorities.

Motion for a European Parliament Resolution on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI))

Because of the steady increase in the need for organ transplantation in Europe, the fact that safety issues are often ignored in illegal commercial organ transplantation and organ trafficking and the rapid growth in transplant tourism, the European Parliament in 2007 launched a new initiative. Following the Commission Communication, on 22 April 2008 the European Parliament therefore adopted a resolution on organ donation and transplantation by a large majority.

73. Directive 2004/23/EC, Recital 3.

74. Annexes: Annex I: Selection criteria for donors of tissues and cells (except donors of reproductive cells) as referred to in Article 3 (a).
Annex II: Laboratory tests required for donors (except donors of reproductive cells) as referred to in Article 4 (1).
Annex III: Selection criteria and laboratory tests required for donors of reproductive cells as referred to in Articles 3 (b) and 4 (2).
Annex IV: Cell and/or tissue donation and procurement procedures and reception at the tissue establishment as referred to in Article 5.

75. http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_council15332_en.pdf.

The European Parliament stressed that it looked forward to the Commission proposal for a directive laying down quality and safety requirements for organ donation, procurement, testing, preservation, transport and allocation across the EU and the resources needed to meet these requirements, but did not wish it to create an additional administrative burden. With regard to organ transplantation, reducing the organ (and donor) shortage were described as the main challenge that EU member states face; the European Parliament therefore looked forward to the Commission's Action Plan for strengthened co-operation between member states in order to "increase organ availability, enhance the efficiency and accessibility of transplantation systems, increase public awareness, and guarantee quality and safety."[76]

The European Parliament pointed out that member states are responsible for their own legal model ("opt-in", "opt-out") and considered it unnecessary to adapt or harmonise legal systems. In any case, it called on member states to achieve the full potential of post-mortem donations.[77] Furthermore, it underlined the need to ensure that organ donations stay strictly non-commercial[78] and endorsed measures which aim at protecting living donors and ensuring that organ donation is made altruistically and voluntarily, thus ruling out payments between donors and recipients, any payment being confined solely to compensation which is strictly limited to making good the expense and inconvenience related to the donation. Member states were called upon to define the conditions under which compensation can be granted.[79] Furthermore, they were urged to adopt or maintain strict legal provisions in connection with transplantation from unrelated living donors, in order to make the system transparent and exclude the possibility of illicit organ selling or coercion of donors.[80]

Additionally, the European Parliament called for a **European donor card**, complementary to existing national systems,[81] and for more international co-operation to promote availability and safety of organs. To underline the importance of increasing public awareness of organ donation and transplantation, it called on the Commission, member states and civil society to enhance structurally the promotion of organ donation[82] and to promote **World Donor Day**.[83] In addition, it favoured the establishment of a transplant hotline with a single telephone number managed by a national transplantation organisation that can be reached 24 hours/day and is staffed with appropriately trained and experienced professionals who can rapidly provide relevant and accurate information.[84]

Lastly, it stressed the necessity to ensure the quality and safety of organ donation and transplantation and to create and develop national regulations and a regulatory framework to enhance quality and safety, without this having a negative impact on the availability of transplant organs.[85]

A separate chapter deals with organ trafficking. The European Parliament highlighted the link between organ shortage and organ trafficking, stating that organ trafficking undermines the credibility of the system for potential voluntary and unpaid donors. It emphasised that any commercial exploitation of organs is unethical and inconsistent with the most basic human values[86] and asked the Commission to fight against the practice of organ and tissue trafficking, including the transplantation of organs and tissues from minors, from the mentally disabled or from executed prisoners[87] and called on the Commission and member states to take measures to prevent "transplant tourism" by drawing up guidelines to protect the poorest and most vulnerable donors from being victims of organ trafficking, adopting measures that increase the availability of legally procured organs and by exchange of waiting list registrations between existing organ exchange organisations to avoid multiple listing.

Additionally, it asked the Commission to promote a common approach which aims at compiling information on national organ trafficking legislation and to identify the main problems and potential solutions.[88] Member states were urged, where necessary, to amend their criminal codes to ensure that those responsible for organ trafficking are adequately prosecuted, including sanctions for medical staff involved in transplantation of organs obtained from trafficking, while making every effort to discourage potential recipients from seeking trafficked organs and tissues; which should include consideration of criminal liability of European citizens who have purchased organs inside or outside the EU.[89]

Lastly, member states were called on to take the necessary steps to prevent healthcare professionals from facilitating organ and tissue trafficking as well as health insurance providers from facilitating activities that directly or indirectly promote trafficking in organs[90] and to sign, ratify and implement the *Council of*

76. Motion for a European Parliament Resolution on organ donation and transplantation: Policy actions at EU level, para 9.
77. Motion for a European Parliament Resolution on organ donation and transplantation, para 12.
78. Motion for a European Parliament Resolution on organ donation and transplantation, para 22.
79. Motion for a European Parliament Resolution on organ donation and transplantation, para 23.
80. Motion for a European Parliament Resolution on organ donation and transplantation, para 24.
81. Motion for a European Parliament Resolution on organ donation and transplantation, para 34.
82. Motion for a European Parliament Resolution on organ donation and transplantation, para 36.
83. Motion for a European Parliament Resolution on organ donation and transplantation, para 40.
84. Motion for a European Parliament Resolution on organ donation and transplantation, para 43.
85. Motion for a European Parliament Resolution on organ donation and transplantation, para 45.
86. Motion for a European Parliament Resolution on organ donation and transplantation, para 49.
87. Motion for a European Parliament Resolution on organ donation and transplantation, para 50.
88. Motion for a European Parliament Resolution on organ donation and transplantation, para 52.
89. Motion for a European Parliament Resolution on organ donation and transplantation, para 53.
90. Motion for a European Parliament Resolution on organ donation and transplantation, para 54.

Europe Convention on Action against Trafficking in Human Beings and the *Trafficking in Persons Protocol* if they have not already done so.[91]

The members of the European Parliament regretted that Europol had not come up with a survey on organ selling and trafficking because it claims that there are no documented cases. Referring to reports of the Council of Europe and WHO which give evidence that the organ trade is also a problem for EU member states, the members of the European Parliament asked the Commission and Europol to improve monitoring of cases of organ trafficking.

Proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM (2008) 818 final, 2008/0238 (COD))

The proposed directive of 8 December 2008 aims at providing a clear legal framework for organ donation and transplantation, minimising the risk for the organ transplant recipients and improving and optimising the allocation of organs across the European Union, as well as providing the transplant surgeon with the necessary information to make the best choice.

This proposal for a directive covers human organs that are used for transplantation, during all the phases of the process – donation, procurement, testing, preservation, transport and use – and aims to ensure their quality and safety and hence a high level of health protection.[92] It excludes blood and blood components, human tissues and cells, as well as organs or tissues and cells of animal origin and relates to the purpose of transplantation only. It aims to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements so as to facilitate their exchange between member states. It proposes that a competent national authority be created or designated in each member state to ensure compliance with EU quality and safety standards. The tasks of such an authority would include the establishment of a traceability system for human organs and a reporting system for serious adverse events and reactions. In addition, data collection on specific organ characteristics would be standardised and national quality programmes would ensure continuous monitoring.

The added values are expected to be ensuring quality and safety for patients at EU level and the protection of donors, as well as facilitating co-operation between member states and cross-border exchanges.

91. Motion for a European Parliament Resolution on organ donation and transplantation, para 55.

92. Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation: Introduction, Recital 12.

The Iberoamerican Network/Council of Donation and Transplantation (RCIDT)

The aim of the Iberoamerican Network/Council of Donation and Transplantation (RCIDT) is the development of co-operation between its members in terms of organisational, legislative, professional-training, ethical and sociological aspects related to donation and transplantation of OTC in Iberoamerican countries. The proposal to set it up was approved at the 7th Iberoamerican Conference of Health Ministers in Granada (Spain) in September 2005 and confirmed a month later at a summit of the Heads of State and Government in Salamanca (Spain). The ONT is in charge of its permanent secretariat. The network is made up of 21 Spanish and Portuguese speaking countries.

To date, the RCIDT has produced eleven recommendations and consensus documents:

- Recommendation Rec RCIDT 2005 (1) on autologous cord blood banks,
- Recommendation Rec RCIDT 2005 (2) on the role and training of professionals responsible for organ donation (transplant donor co-ordinators),
- Recommendation Rec RCIDT 2005 (3) on the functions and responsibilities of a National Transplant Organisation,
- Recommendation Rec RCIDT 2005 (4) on Quality Assurance Programmes in the Donation Process,
- Recommendation Rec RCIDT 2005 (5) on the Training Plan for training professionals in donation and transplantation,
- Recommendation Rec RCIDT 2006 (6) on solutions to organ shortage (phases of the deceased donation process – areas for improvement),
- Consensus Document: Criteria to prevent the transmission of neoplasic diseases through transplantation,
- Recommendation Rec RCIDT 2007 (7) on guides for the quality and safety of cells and tissues of human origin for transplantation,
- Recommendation Rec RCIDT 2008 (8) on bioethical considerations on donation and transplantation of organs, tissues and cells,

- Recommendation Rec RCIDT 2008 (9) on harmonisation of criteria for the diagnosis of brain death in Iberoamerica,
- Declaration against transplant tourism in Latin America.

Of particular interest is Recommendation Rec RCIDT 2008 (8) on bioethical considerations on donation and transplantation of organs, tissues and cells, which was approved at the 6th meeting of the Council in Havana from 26 to 28 May 2008. In this recommendation, the RCIDT sought to define a set of ethical principles to be followed by its members in connection with the organisational and legislative measures concerning the donation and transplantation of OTC.

World Medical Association

In October 2006, the 58th WMA General Assembly in Pilanesberg (South Africa) revised the World Medical Association Statement on Human Organ Donation and Transplantation which had been adopted by the 52nd WMA General Assembly in Edinburgh (Scotland) in October 2000. In the light of advances in medical sciences which have made possible a significant increase in successful organ transplantations, the WMA developed a policy based on ethical principles to provide guidance to medical associations, physicians and other healthcare providers, as well as to those developing policy and protocols regarding these issues. In the statement, the WMA underlined the need to improve organ donations and measures to ensure that donor choice takes place on a free and informed basis without any pressure or coercion.

The universal principle of non-commercialisation of organ transplants was also expressly reiterated: in paragraph 30, the WMA clearly stated: "Payment for organs for donation and transplantation must be prohibited. A financial incentive compromises the voluntariness of the choice and the altruistic basis for organ donation. Furthermore, access to needed medical treatment based on ability to pay is inconsistent with the principles of justice. Organs suspected to have been obtained through commercial transaction must not be accepted for transplantation. In addition, the advertisement of organs in exchange for money should be prohibited. However, reasonable reimbursement of expenses such as those incurred in procurement, transport, processing, preservation, and implantation is permissible."

In paragraph 31, reference is also made to the (ethical) obligation on doctors: "Physicians who are asked to transplant an organ that has been obtained through a commercial transaction should refuse to do so and should explain to the patient why such a medical act would be unethical: because the person who provided the organ risked his or her future health for financial rather than altruistic motives, and because such transactions are contrary to the principle of justice in the allocation of organs for transplantation."

D. National legislation on organ transplantation

Laws and regulations are a crucial basis of national organ donation and transplantation services to protect the live donor and the transplant recipient, as well as to meet patients' needs while maintaining society's principles. The donation of human material for transplantation must be defined by law. This applies to procurement from deceased citizens and residents as well as to donations from live donors. A legal framework for transplantation provides a clear structure for the organisation in charge of donation, allocation and transplantation of OTC, including national co-ordination of the service, but also for its overview by authorities. Indeed laws and regulations set requirements to comply with ethical principles as well as to achieve quality, safety and effectiveness. National transplantation laws are necessary instruments to combat trafficking in organs tissues and cells.

The Global Observatory on Donation and Transplantation is a result of the collaboration between the ONT, the Spanish transplantation organisation and the WHO. The Observatory provides a global database on legal and organisational framework for donation and transplantation services in member states, as well as on donation and transplantation activities throughout the world.

So far, the Observatory includes data on 105 member states representing 89 % of the global population and more than 99 % of the global organ transplantation activity. There is specific legislation on donation and transplantation in 91 countries. Kidney transplantation takes place in 7 out of 14 countries devoid of any legislative framework.

The law prohibits giving or receiving payment for organs (including any other compensation or rewards) in 55 countries (60%). Of these 55 countries, 52 have defined penalties for commerce in donated organs. However, expenditure associated with live donations are covered in 62 countries out of 91 (68%) so that donors do not have to pay in addition to their donation. It is worth noting that 42% of countries do not have a legal requirement for traceability of the organ and that in 54% of countries the law does not mandate control of importation and exportation of organs.

Within the last four years several countries have adopted legislation or amended existing legislation on donation and transplantation to better combat organ trafficking and traffic in human beings for the purpose of organ removal, transplant tourism and commercialism in transplantation. Major progress has been achieved in countries where organ trafficking and transplant tourism was thriving in 2005 due to lack of legal prohibition of commercial transplantation. In April 2007 the State Council of China adopted a donation and transplantation law whereby *inter alia* it prohibits commercial transplantation and sets up effective overview of hospitals carrying out transplantations. In September 2007 an Ordinance signed by President Musharaf of Pakistan also provided a framework for donation and transplantation activities which prohibits financial gain from the human body and its parts, aimed at stopping the exploitation of vulnerable persons for the benefit of wealthy foreigners in need of a kidney. In the Philippines the implementing rules and regulations for the organ trafficking part of the human trafficking law became effective on 21 June 2009. It quotes the 1991 WHO Guiding Principles "The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited." (Article IV, section 6). Egypt is also progressing towards defining a legislative framework as the People's Assembly has approved a new transplantation law banning commercialism in transplantation that could be adopted before the close of the current parliamentary session.

The responsibility to meet patients' needs in organs for transplantation from national resources whenever possible leads to improved effectiveness of donation and transplantation services in many countries, including by introducing legislation and amendments to existing legislation to increase donation after death and reinforce organisations. For instance Japan adopted, in June 2009, an amendment recognising the definition of death on neurological criteria and simplifies consent to donation. The Republic of Korea is also planning to initiate this year a revision of the law in order to simplify consent for donations from deceased donors.

Despite new efforts towards self sufficiency in organs for transplantation, many patients are not transplanted or have to endure long delays on waiting lists in all countries. Desperate patients remain tempted to by-pass national systems and to obtain a transplant through organ trafficking or transplant tourism. Countries where foreign patients were welcome have now set legal barriers. However transplant tourism, fuelled by hefty profits, continues undercover and illegally, but probably at a much reduced scale. Both in China and in Pakistan enforcement authorities have penalised institutions and individuals carrying out illegal transplantation and have to combat adversaries determined to hold on to their profits.
Other countries have initiated major onslaughts on clandestine or camouflaged illegal organ transplantation as in the Gurgaon case in India in 2008 or recently, in July 2009, in the United States.
Now that transplant tourism has to go into hiding even in countries where it was thriving a few years ago, the only way to identify illegal transplantation at large is through the collaboration of national authorities with professionals. The Executive Board of WHO in its 124th session in January 2009 adopted Resolution EB124.13 on "Human Organ and Tissue Transplantation" to be presented to the World Health Assembly in 2010. This resolution urges member states to oppose commercialism, organ trafficking and transplant tourism, "including by encouraging healthcare professionals to notify relevant authorities when they become aware of such practices in accordance with national capacities and legislation".

E. Organisational measures

Council of Europe

At the Council of Europe, the **Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO)** was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects of organ transplantation. The conference considered that the organisational aspects of organ transplantation were particularly important in meeting the organ shortage and that European co-operation was needed to ensure efficient organisation.

Carrying forward the work of the SP-CTO, the Council of Europe **Steering Committee on Organ Transplantation (CD-P-TO)** was set up under the aegis of the European Directorate for the Quality of Medicines and Healthcare (EDQM) and held its first meeting on 17 and 18 April 2007. The work programme includes the establishment of a working group to discuss the revision and updating of the *Guide to Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells*.

Through its activities in the field of transplantation, the Council of Europe contributes actively to the implementation of high standards for the protection of public health and for the promotion of human rights and dignity. The committee focuses on elaborating and promoting the principle of non-commercialisation of organ donation, strengthening measures to avoid organ trafficking and, in general, elaborating high ethical, quality and safety standards in the field of organ transplantation.

These activities include communications at international specialist meetings, publications (e.g. *Guide to safety and quality assurance for the transplantation of organs, tissues and cells* – 3rd edition (2007)), surveys and international data collection (e.g. *Transplant newsletter*, annual survey of figures for organ donation and transplantation in Europe, Latin America, Australia, Canada and the United States), the organisation of visits to countries to help them implement programmes for promoting compliance with the relevant Council of Europe resolutions and conventions and the preparation of drafts which serve as a basis for Committee of Ministers resolutions.

Carrying forward the work of the former Committee of Experts in Blood Transfusion and Immunohaematology (SP-HM), the Council of Europe **Steering Committee on Blood Transfusion (CD-P-TS)** was set up under the aegis of the European Directorate for the Quality of Medicines and Healthcare (EDQM) and held its first meeting on 20 and 21 March 2007. The steering committee appointed a working group to discuss the revision and updating of the *Guide to the preparation, use and quality assurance of blood components*.

Since 1998, the Council of Europe has organised **European Organ Donation Day** in a different country every year (1998: Austria, 2000: Cyprus, 2002: Portugal, 2003: Greece, 2004: Sweden, 2005: Switzerland, with the 1st World Organ Donation Day, 2006: Turkey, 2007: Ireland, 2008: Slovenia). The European Day for Organ Donation and Transplantation will take place in Germany in 2009 and Georgia in 2010. A booklet for national authorities on living donor transplantation prepared by a working group was scheduled for publication by the end of 2008. It will recapitulate the relevant Council of Europe recommendations and resolutions and give state-of-the-art information available in fields not yet covered.

The Council of Europe Select Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO) in 1996 defined the solution of the deceased organ shortage as its main priority for future actions. The first draft of the document "*Organ Shortage: Current Status and Strategies for the Improvement of Organ Donation – A European Consensus Document*"[93] was prepared and approved by the committee after being circulated among transplant professionals and international scientific societies. The document was subsequently analysed by all member states and approved by the Health Committee.

93. http://www.edqm.eu/medias/fichiers/Organ_shortagecurrent_status_and_strategies_for_improvement_of_organ_donation_A_European_consensus_document.pdf.

The purpose of the document is to provide an analysis of, and guide to, the steps required to procure the maximum number of high-quality organs for transplantation, taking into account the available scientific evidence and describing relevant international experience. The document focuses on the technical and organisational aspects of deceased organ donation. Some of the aspects covered by this comprehensive document have been further developed by the SP-CTO and the CD-P-TO in specific recommendations summarised previously.

European Union

The *Communication from the Commission "Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Co-operation between Member States" (COM (2008) 819 final)*)[94] concerns a six-year plan with ten priority actions addressing the three key challenges in organ donation and transplantation in Europe: improving the quality and safety of organs across Europe, increasing organ availability and making transplant systems more efficient and accessible. It will promote strengthened co-operation between member states based on the identification and development of common objectives, guidelines, indicators and benchmarks and on identification and sharing of best practices. On the basis of these actions, member states should develop their own sets of national priority actions. A mid-term review (mid-term review 2012) of the actions will be carried out to evaluate the efficacy of the action plan.
The following priority actions are indicated:

- Priority action 1: Promote the role of transplant donor co-ordinators in every hospital where there is potential for organ donation.
- Priority action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.
- Priority action 3: Exchange of best practices on living donation programmes among EU member states: Support registers of living donors.
- Priority action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.
- Priority action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.
- Priority action 6: Enhancing the organisational models of organ donation and transplantation in the EU member states.
- Priority action 7: Promote EU-wide agreements on aspects of transplantation medicine.
- Priority action 8: Facilitate the interchange of organs between national authorities.
- Priority action 9: Evaluation of post-transplant results.
- Priority action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.

Furthermore, the European Commission's Directorate-General for Health and Consumers funded and co-funded several projects on organ donation and transplantation,[95] including:

- European Training Programme on Organ Donation (ETPOD): a project aimed at designing a corresponding professional training programme;[96]
- European living donation and public health: aimed at helping to reach a consensus on legal and ethical standards regarding protection and registration practices relating to living organ donors;[97]
- Alliance-O-project: an ERANet co-ordination action, which was financed for three years (2004-2007) by the European Commission and involved institutions from seven EU member states: France (Agence de la biomédecine), Germany (Deutsche Stiftung Organtransplantation), Hungary (Hungarotransplant Psc), Italy (Istituto Superiore di Sanità, Centro Nazionale Trapianti), Portugal (Organização Portuguesa de Transplantação), Spain (Organización Nacional de Trasplantes y Medicina Regenerativa) and United Kingdom (UK Transplant).[98] It addressed questions regarding the co-ordination of national programmes in organ transplantation and produced position papers on the following issues: expansion of donor pools, allocation rules and equity, increasing safety and quality of organ transplantation, evaluation of transplantation performance, fundamental research activities, and ethical and legal aspects;
- European Registry for Organs, Tissues and Cells (EUROCET): aimed at collecting and publishing figures on corresponding donation and transplantation activities;[99]
- DOPKI – Improving the knowledge and practices in organ donation: addressing the problem of

94. http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf.
95. http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/useful_information.pdf.
96. http://etpod.il3.ub.edu/etpod.html.
97. http://www.eulivingdonor.eu/.
98. http://www.alliance-o.org/.
99. http://www.eurocet.org/.

organ shortage and developing a common methodology to improve organ donation rates;[100]

- Reprogramming the Immune System for Establishment of Tolerance (RISET): aimed at research regarding ways to improve acceptance of the transplant by the human body;[101]
- Transplantation Research Integration in Europe (TRIE): a Specific Support Action supported by the 6th EU-RTD Framework Programme aimed at developing a coherent strategy for integrating research in transplantation in Europe, namely by means of identifying priorities in the field of transplantation research, focusing on themes common to cell and solid organ transplantation and by providing recommendations to the EC regarding priority actions to be implemented.[102]

100. http://www.dopki.eu/.

101. http://www.risetfp6.org/cgi-bin/WebObjects/Awo3.woa.

102. http://www.transplantation-research.eu/cgi-bin/WebObjects/Trie.woa.

Iberoamerican Network/Council of Donation and Transplantation (RCIDT)

The RCIDT believes that organisational aspects are especially relevant for tackling the shortage of organs for transplantation and that co-operation is essential for achieving maximum effectiveness of the systems. Its activities are based on scientific advances and individual human values.

Since its establishment in October 2005, the RCIDT has held seven meetings which have been complemented by ongoing interaction between its members involving frequent discussion of the key issues through a sophisticated IT platform, and has produced several recommendations and documents.

The RCIDT regards training as essential and has developed a training programme in aspects related to donation and transplantation activities. Through this ALIANZA master's course in donation and transplantation, professionals put forward by the various health ministries in Latin America countries are trained as transplant coordinators in Spain. The course has been run annually since 2005 and so far almost 150 professionals have been trained, all of whom are already working in their countries and many of whom occupy positions of responsibility at a national level.

Alongside the ALIANZA master's course, training courses on specific aspects of the process of deceased donation and transplantation have been held or are due to be held in Argentina, Chile, Uruguay, Mexico, Ecuador, the Dominican Republic, Colombia, Cuba and Guatemala. Additionally, training actions are planned or are in progress in Central America and the Caribbean. In particular, a programme for Central America and the Caribbean on training trainers in the communication of bad news was launched in April 2008. Under these programmes, teams of monitors are being trained in Cuba, the Dominican Republic and Venezuela and will be able to develop courses in their own countries and in others in the region. Lastly, as part of this broad training programme, courses on quality and safety in the management of tissue banks are also being developed, with wide levels of acceptance and increasing demand, mainly in countries of the Southern Cone.

The problem of practices such as trafficking and transplant tourism which are occurring in some of the countries in the region was raised at the meeting of the RCIDT in Havana in May 2008. Since its inception, the RCIDT has expressed its complete opposition to these practices, which facilitate transplant commerce, and has condemned them as morally unacceptable because they lead to the obvious exploitation of the poorest and most vulnerable groups. The RCIDT is providing specific support to the organisations in charge of overseeing donation and transplantation activity in countries affected by these problems so that they can be tackled more effectively. This support was confirmed in the Declaration against Transplant Tourism.

The following results of the process and the various activities developed by the RCIDT should be mentioned:

- Donation and transplantation organisations have been set up, restructured or revived in countries which lacked this type of system or where there was little or no activity. These organisations depend on or are supported by the health authorities, following the Spanish model, and are being organised as a co ordination network.
- Training activities for co ordinators are being consolidated, through the ALIANZA master's, and courses conducted in Latin America in co operation with several countries. Training is being focused on the different areas in the region and tailored to their specific needs.
- Initiatives to harmonise criteria, in agreement with scientific societies and in accordance with international standards, are being developed, focused on a wide number of aspects, including diagnostic criteria for brain death and clinical evaluation criteria for possible donors.
- The RCIDT is being established as a technical, ethical, training and co operative benchmark for the

development of transplant programmes in all the countries in the region.

- At the same time, deceased donation activities are progressively increasing in countries in the region, the most notable change being from 2005 to 2006: in just a single year, deceased donation activities increased by as much as 60% in Colombia, 30% in Cuba, 27% in Venezuela, 22% in Chile, 20% in Uruguay and 11% in Argentina. Uruguay achieved deceased donation rates close to those described in the United States.

The RCIDT has ensured closer ties between health care authorities and professionals in charge of donation and transplantation in Latin America, providing a basis for the region to take on a leading position in the world regarding donation and transplantation activities.

This section on national legislation may be summarised in the following key points:

- There is an impressive range of existing recommendations, resolutions and international legal instruments dealing with transplantation of OTC. There are no discrepancies between these instruments and they complement one another in an internationally recognised body of law.
- From the outset, the general principles have been very clear: the preference for organs and tissues from deceased persons over those from living persons, the prohibition on making financial gain from the human body and its parts, the vital importance of valid consent and the need to promote altruistic donations and establish appropriate professional standards. These principles are upheld by all major international organisations dealing with this topic: the WHO, the Council of Europe, the EU and the recently founded RCIDT.
- The need to develop an effective deceased donation programme to cover the transplantation needs of the population is clearly recognised by all these international organisations. In addition, organisational measures to increase organ availability from deceased organ donors have been reflected in recommendations, consensus documents and specific actions and activities related to training, education and promotion.

III. Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of organ removal

As already pointed out in the introduction to this study, in public debate and in publications and legal documents, trafficking in OTC and trafficking in human beings for the purpose of organ removal are often mixed up or dealt with together. This leads to confusion both in theory and in practice and consequently hinders effective efforts to combat the two categories of crime and also provide comprehensive victim protection and assistance. Of course, some cases of trafficking in OTC result from trafficking in human beings. However, trafficking in OTC is broader in scope than trafficking in human beings for the purpose of organ removal. On the other hand, trafficking in human beings covers not only exploitation for the purpose of organ removal but also other forms of exploitation. For effective prevention, protection and prosecution, it is necessary to distinguish between trafficking in OTC and trafficking in human beings for the purpose of organ removal so that a targeted approach to the two problems can be developed and implemented.

The link between trafficking in OTC and trafficking in human beings for the purpose of organ removal has not been clearly established. This part of the study provides an overview of the two problems and the legal framework dealing with them. To begin with, it should be noted that there are several similarities between the two, but also certain differences.

The similarities between trafficking in OTC and trafficking in human beings include the root causes, which are mostly the same: shortage of organs to meet demand for transplantation, inequities in health care and poor economic and other conditions that put persons in vulnerable situations. They often therefore end up finding it hard not to agree to take part in the proposed activities and (seemingly) to consent – however comprehensive, detailed and correct their knowledge about what awaits them might be. Selling an organ sometimes seems to be the only way out of a miserable economic situation. In addition, some individuals are in family or cultural relationships where other people decide what happens to them and where those people either offer or deliver them to traffickers for sexual or labour exploitation or to brokers or to hospitals involved in illegal organ transplantations or consent to their being exploited sexually or for labour purposes or to their organs being removed.

The consequences for the individuals are also similar: they face stigmatisation and discrimination in their communities for "what they have done" or "what has happened to them". When they return to their own environment they have to live with the fact that other people there know that they have sold (part of) their body or that something (their sexual integrity or organs) has been taken from them involuntarily – both of which are morally sensitive issues. And they face long-term consequences regarding their physical health and bodily integrity. In the case of the removal of organs, this results from the intervention, as many of the donors encounter medical problems after it, in particular if there is no follow-up medical care, as often applies in trafficking cases. These persons also face consequences in psychological terms: they are often traumatised and feel ashamed.

The fundamental difference between the two cases lies in the fact that trafficking in organs is a crime where the organ and the use of it are the central elements; it does not matter whether the organ has been removed from a living or a deceased donor. In contrast, trafficking in human beings is a crime where the exploitation of an individual is the central aspect and where a combination of three elements (action, means, purpose; see below) has to apply in order for the crime to be constituted. Therefore, trafficking in human beings for the purpose of organ removal can only be committed if organs are removed from living donors in one of the cases mentioned in the definition.

As the exploitation of the victim results in the removal and further use of an organ, a case of trafficking in organs (and thereby both offences) also applies. However, as the aim of the two crimes is not the same, they overlap but differ in scope. Trafficking in organs can be committed separately from trafficking in human beings, e.g. if organs are removed from deceased donors or if no illegal activities or means have been used with respect to a living donor but, e.g., if the requirements for legal interven-

tions and transactions have been infringed.

Additionally, *per definitionem*, trafficking in human beings for the purpose of organ removal is limited to removal of organs; all of the documents (the United Nations Trafficking in Persons Protocol, the Council of Europe Anti-Trafficking Convention and the Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography) only mention the removal of organs and none makes any reference to cells or tissues. The *travaux préparatoires* to the United Nations Trafficking in Persons Protocol show that the discussions did, indeed, cover the issue of broadening the scope to include the removal of cells, tissues and body parts, but, ultimately, the decision was taken only to include the removal of organs in the definition, so all provisions regarding trafficking in human beings refer to cases of the removal of organs only.

More specifically, all provisions regarding criminalisation and assistance to and protection of victims must be implemented on an obligatory basis for cases of trafficking in human beings for the purpose of organ removal only. However, it should be made clear that this does not prevent states broadening the scope, as even the definition of trafficking in human beings itself provides that exploitation should include "at a minimum" the purposes listed. This indicates clearly that the drafters did not wish to restrict the scope to the purposes listed. States are therefore free to include the purposes of removal of cells, tissues and body parts in national legislation.

Because of these situations, it is necessary to look at the framework both for trafficking in OTC and for trafficking in human beings for the purpose of organ removal so as to analyse which provisions already exist, where there are loopholes in international instruments and which measures are missing.

A clear distinction between the two crimes is also needed, on the one hand, to better prevent and prosecute such acts and especially because the needs of victims can be completely different. Living donors involved "only" in trafficking in OTC have certain needs for protection and care, but living donors who fall victim to trafficking in human beings for the purpose of organ removal need a far more comprehensive protection regime, as they have been affected by a serious crime. On the other hand, deceased donors do not need such protection measures at all, but there must be a system in place to prevent illegal activities and unethical behaviour, among other reasons, because of the serious damage that these activities cause to the image of donation and transplantation, which further heightens organ shortage by precluding altruistic donation.

In **Current situation and consequences**, below, the extent of the problems of trafficking in organs and trafficking in human beings for the purpose of organ removal and their consequences will be dealt with jointly, while the international standards and initiatives regarding organ trafficking and the application of the international standards regarding trafficking in human beings for the purpose of organ removal will be dealt with separately under **Trafficking in OTC: international standards and initiatives** (page 65) and **Trafficking in human beings: international standards and their application to organ removal** (page 76).

A. Current situation and consequences

Trafficking in OTC and trafficking in human beings for the purpose of organ removal – known facts

Trafficking in organs and trafficking in human beings for the purpose of organ removal

While there is information about the legal activity in organ donation and transplantation, for many countries the numbers regarding victims and trafficked organs remain rather incomplete. Both the quantitative and also the qualitative description of trafficking in organs and trafficking in human beings for the purpose of organ removal are hindered by the lack of universal agreement about what is involved in the former and by the limited amount of detailed information available from official sources.

There is possibly therefore a high number of unreported cases for the two crimes. This is because of the huge profits and rather low risks for the perpetrators. Victims/donors are also mostly ashamed and frightened to report cases, recipients of organs will remain silent and the other people who know about the interventions are mostly directly involved in the trafficking offences; thus it is very difficult to investigate the crimes. The numbers and trends available are therefore mostly based on estimates and rumours, as well as on certain official data which – as already pointed out – remain incomplete.

When describing practices in trafficking related to transplantation, it should first be noted that this form of trafficking, either in organs or in human beings for the purpose of organ removal, is a global issue. There is an international bioethical framework which is properly reflected in existing standards. In addition, transplantation needs are universal, but are dealt with unequally by individual countries, in spite of those standards. Trafficking here commonly therefore involves different countries and usually takes advantage of a situation in which particular countries do not have a well developed or implemented regulatory framework to prevent trafficking and protect the live donor. Although the simultaneous involvement of different countries in these practices is possibly the commonest form of trafficking related to organ transplantation, there are cases confined to specific nations involving national donors and recipients.

In this connection, prosperous Asians began travelling to parts of Southeast Asia to obtain organs from poor donors – an early form of ethically suspect "transplant tourism". These practices were documented by many media organisations which showed that few benefits accrued to the very poor persons who sold a kidney. Concerns were also raised about poor outcomes associated with organs bought from these very poor persons. This was probably the earliest known case of a practice possibly related to trafficking in persons for the purpose of organ removal for transplantation purposes.

In 1997, the Bellagio Task Force headed by the American anthropologist Nancy Scheper-Hughes, whose members included physicians, surgeons, human rights activists and scholars, met in Bellagio (Italy) to discuss transplantation, bodily integrity and reports of global organ trafficking and trafficking in human beings for the purpose of organ removal.[103] After the meeting, WHO, the WMA, the Council of Europe, the UN, the Transplantation Society and other organisations and societies convened conferences to discuss current laws, practices and procedures.

Today, many countries throughout the world have been alleged to be among the world's leading providers of trafficked organs. Other countries are increasingly having to deal with the situation of nationals travelling abroad to obtain trafficked organs. Most of them come back to their countries of origin for post-transplant follow-up care. A comprehensive update on the current state of what was named "the international organ

103. Rothman, DJ et al. The Bellagio Task Force Report on Transplantation, bodily integrity and the international traffic in organs. Transplant Proc 1997; 29: 2739-2745.

trade" was given at the Second Global Consultation on Human Transplantation[104] at WHO headquarters in Geneva in March 2007 and subsequently published.[105]
Yosuke Shimazono presented the results of research into trade related to transplantation, based on a systematic review of different available sources during a five year period, including academic journals, media sources, transplant tourism websites, transplant registries and reports from health authorities. He found only 309 "relevant" documents, of which 243 were media reports and emphasised the need for "further medical and social scientific research," without which he thought this "global health issue" could not be addressed effectively. Practices described clearly fell under the scope of trafficking in organs, but sadly, it did more frequently fall under that of trafficking in human beings for organ removal.

The form described most frequently occurs in the context of what has been called "transplant tourism". Transplant tourism usually involves travel from rich countries in the North to poor countries in the South, with wealthy recipients desperate to find a quick solution to their need for an organ travelling to mostly developing countries, where impoverished and vulnerable people sell organs to solve their desperate economic needs. The term "transplant tourism" obviously fails to capture the ethical issues related to this practice, but has been widely used in international health discussions. There have been other types of travel by potential donors and recipients in connection with trade in organs. Cases reported either describe the potential donors travelling to the recipient's country or both the donor and recipient travelling to another country where the transplantation procedure is then performed.

Most of the cases described concerning organ trade and transplant tourism are either cases of trafficking in organs or cases of trafficking in human beings for the purpose of organ removal. The procedures are usually facilitated and organised by intermediaries, either in the countries of origin of the potential recipients or in the destination countries. Recipients are offered the possibility of transplantation in different ways here, even by healthcare professionals in charge of them. Recently, many of these "services" have been offered openly through dedicated websites in form of "packages" including the travel and the transplantation procedure itself. The price of "kidney packages", for example, may range from US$70 000 to US$160 000. These websites are easily found on the Internet. On the other hand, "donors" are usually, but not always, recruited in their countries of origin. There have been cases reported in which donors are recruited and transferred to other countries, where the organ extraction and the transplantation procedure takes place. According to the various sources, the intermediaries involved in this entire process have included individual agents, travel agencies, hospitals, healthcare professionals and even embassy officials. It should therefore be emphasised that underlying corruption is present in many countries. Sometimes, previous victims of trafficking are involved in the recruitment of donors. In many instances, family members act also as intermediaries in such recruitment when they have any kind of power to do so. Notably, it has been repeatedly denounced that donors are not sufficiently or completely informed about the procedure, if any information is provided at all. It seems also a frequent practice that the donor is not paid as initially promised. The amount received in general terms is quite low compared to what was paid by the recipient, the majority going to the professionals and intermediaries involved. Hence, abuse, fraud and coercion are common.

In Shimazono's report, several countries were highlighted as "organ-exporting", meaning those where organs from local donors are transplanted into foreigners through purchases or sales. Most of the countries in this category do not have a legal framework in place or duly implemented to ban and prosecute trafficking in organs and trafficking in human beings for the purpose of organ removal. Moreover, they also lack systems for protecting live donors properly against coercion, abuse or exploitation. In some cases, legislation has been passed in this connection and has been followed by a decrease in trafficking-related activities. However, this has been followed by an increase in transplantation to foreigners, presumably as a result of trafficking, in other countries. However, it is well described that practices still remain in many of these countries despite the enacted law, since there are no effective mechanisms to prevent and prosecute them. This gives an idea of the loopholes that exist for perpetrators. Organ-exporting countries are basically located in Africa, Asia, eastern Europe and South America. In contrast, many western European and North American countries and some rich Asian countries, among others, are currently known to have nationals travelling abroad every year for purchased organs ("organ-importing countries").

Estimates have been carried out regarding the quantitative significance of these various practices. On a global level, it is estimated that up to 5%-10% of kidney transplants performed annually around the world are the result of trafficking. Given the Global Observatory on Donation and Transplantation's estimate of overall activity of about 68 000 kidney transplants a year, this would mean that 3 400-6 800 kidney transplants are being carried out on the basis of these

104. http://www.who.int/transplantation/publications/ReportGlobalTxConsultation_March_2007.pdf.
105. Yosuke Shimazono. The state of the international organ trade: a provisional picture based on integration of available information. Bulletin of the World Health Organization 2007; 85: 955–962.

forms of trafficking, which is obviously a quantitatively significant figure, although still possibly an underestimate.

The better known form of trafficking related to organ transplantation unfortunately usually involves living unrelated donors. These cases mainly fall under the scope of trafficking in human beings for the purpose of organ removal. However, as previously stated, there are reports which involve deceased donors. This has been the case in some South American and Asian countries, where organs from deceased donors have been provided on a commercial basis for foreigners requiring transplants, including kidneys, livers and hearts. There is a well-known example of an Asian country where organs from executed prisoners have allegedly been used for the majority of the transplants performed in the country. Doubts concerning the validity of consent obtained from the executed prisoners, as a vulnerable group, and the fact that organs were mainly allocated to foreigners might lead this practice to be regarded as a particular form of trafficking in organs.

While knowledge of practices in organ trafficking and trafficking in human beings for the purpose of organ removal is gradually improving and although precise data are still lacking, it is important to point out that several of the governments concerned have been taking specific measures to combat these practices, taking international standards as a reference. Hence, several countries have issued new legislative frameworks which address, among others, the requirements for medical centres for transplant services, ban financial compensation to organ donors, ensure priority to nationals as transplant recipients and protect the living donor. While these new legislations represent a clear compromise from governments to prosecute these crimes, it remains to be proven that efforts are being made in their practical implementation.

Trafficking in tissues

Human tissues are sold across national boundaries worldwide, but this activity is not explicitly banned in any country since the charges or costs relate to handling and processing rather than the direct purchase of human tissues. However, trafficking in tissues has been more widely described than trafficking in organs. The fact that donation and transplantation of tissues is less complex than in the case of organs in terms of restrictions affecting ischaemic times and storage possibilities makes trafficking in tissues more feasible than organ trafficking. There are reports about the finding of corpses lacking certain pieces of anatomy.[106] Far from representing irrefutable proofs of trafficking in organs, what lies behind these and other cases is possibly the obtaining of material susceptible of being converted into implantable tissues either directly (corneas) or after cryopreservation or lyophilisation (heart valves, bones, ligaments, dura matter, etc). Those responsible for these practices are international brokers supplying tissues to the powerful industry in human tissues.

The use of tissue in modern medicine is massive and is set to increase in the future. However, the main difference from organs is that there is no scarcity of tissue at least in general terms and, when there is a shortage, it is the result of an organisational problem and a lack of will or a failure to allocate human and material resources to ensure tissue procurement. In this context, quite apart from the related ethical and legal problems, the fraudulent use of cadavers poses a major risk of transmission of diseases, which are sometimes not detectable with routine analytical procedures. This is because many risk situations involving the transmission of diseases through the transplantation of organs and tissues can only be reasonably ruled out through a careful clinical history performed either on the donor during his lifetime or on his relatives after his death.

A recent example of tissue trafficking was revealed involving a company which supplied human tissues for transplantation. The company was discovered to be paying some funeral homes to obtain all types of tissues from cadavers through irregular and unsafe practices. Several documents/certificates were forged, including those related to the consent to organ donation and to the cause of death. This highlights that trafficking in organs and tissues involves not only ethical and legal problems but also public health threats, since the tissues procured and distributed in this case had obviously not undergone any types of checks for transmissible infectious or tumoral diseases.[107]

Socio-demographic issues of trafficking in human beings for the purpose of organ removal: is there a gender issue?

Lack of data regarding current figures on trafficking related to transplantation also hinders research regarding whether there is a socio-demographic issue, in particular a gender issue, related to trafficking in human beings for the purpose of the removal of organs. Trafficking in human beings for any purpose easily affects the most vulnerable groups in a population and this could also be the case for trafficking in human beings for the purpose of the removal of organs. Few data available provide the impression that the gender issue, if it does exist in this case, might vary from country to country relying basically on cultural and societal issues. This should be outlined under the general conception that live donation is, even under legal circumstances, more frequently performed by females. Why this occurs

106. In Pearson (#20). Chaudury, V. Argentina uncovers patients killed for organs. British Medical Journal 1992; 34: 1073-1074.

107. Centers for Disease Control and Prevention (CDC). Brief report: investigation into recalled human tissue for transplantation – United States, 2005-2006. MMWR Morb Mortal Wkly Rep 2006; 55: 564-566.

might respond to several causes, among others because males are more prone to develop end stage renal disease than females.

Taking that concept as a general statement, some available reports have confirmed the female predominance as commercial living donors in some Asian countries. In a survey performed in India of 305 commercial living donors, 71% of them were female.[108] When they were asked why they had acted as commercial living donors instead of their spouses, the most frequent reason proffered was that the man was the breadwinner and/or that he was ill. Two women admitted that their husband had obliged them to "donate". The authors stressed that since the survey was performed in front of some family members, the cases of women who could have been forced to donate was possibly higher.

However, the female predominance in the available reports is not constant. As a matter of fact, a majority of males as commercial living donors has been observed in studies performed in other countries, such as Egypt[109] or Iran.[110]

Therefore, available information does not allow us to conclude that there is a gender issue related to trafficking in human beings for the purpose of organ removal. What can be said is that commercial living donors do have a baseline poor economical status, many are labourers or street vendors and frequently are living below the poverty line. This is obviously a sad fact when financial gain, rather than altruism, is the underlying reason for "donating" an organ. Commercial living donors are frequently illiterate, which makes them especially vulnerable.

108. Goyal M, Mehta RL, Scheneiderman LJ, Sehgal AR. Economic and health consequences of selling a kidney in India, JAMA 2002; 5: 29-73.

109. Budiani D. Consequences of living kidney donors in Egypt. 10th Congress of the Middle East Society for organ transplantation; 2006 Nov 26-29, Kuwait.

110. Zargooshi J. Quality of life of Iranian kidney "donors". J Urol 2001; 166: 1790-9.

Myths concerning trafficking in OTC and trafficking in human beings for the purpose of organ removal

Trafficking in OTC and trafficking in human beings for the purpose of organ removal are a dramatic reality that has been added to the tragic miseries of humanity during the last decades. However, there are also stories surrounding the two crimes that have never been realistically proven and are easy to dismantle through clear technical arguments.[111] It is important to highlight these stories to clearly distinguish the myths from the facts.

The stories about tourists waking up to find a kidney stolen or young children being kidnapped or adopted and then killed so that their organs can be used for transplantation can clearly be categorised as myths. These stories, which are frequently reported in the media, generate a state of alarm at an international level. Indeed, rumours grew so intense on some occasions that there were attacks on North Americans in Latin American countries in the early 1990s because they were suspected of trafficking children for the purpose of organ removal.[112]

United States government agencies issued denials concerning these practices.

There are several variations of the basic organ-theft urban legend. The most common one involves a business traveller to some big city, who takes a break after a long day and has a drink in a hotel bar. A prostitute approaches him and they flirt. They end up in his hotel room, where he soon blacks out. He wakes up the next morning in the hotel room's bathtub to find a note taped to the wall instructing him to call the emergency services from a nearby telephone. He does, and the emergency operator instructs him to feel for a tube protruding from his lower back. He finds one, and begins to panic. He is told to lie still, as one of his kidneys has been removed, and that an ambulance is on the way. He is later told of a vicious gang of kidney thieves who sold his kidney to the highest bidder in a clandestine organ market. In some cases, the tub is filled with ice; in others, the man discovers the sewn-up incision on his own, without a note or emergency call.[113]

A second type of organ-snatching urban legend – and the one repeated most often – involves the removal of organs from children. These cases are even more horrifying because the victim is a defenceless child. A typical claim is that children from countries in Asia, Latin America or Africa are kidnapped and sold to rich Americans or Europeans for their organs. The most commonly claimed thefts are those of kidneys and corneas.[114] It must be said that these legends are constructed on a basis that confers them some degree of credibility: thousands of children worldwide disappear as a result of violent acts or are simply sold by their own parents and then sold on for adoption or for sexual or labour exploitation. Sometimes they are simply killed on the streets in some countries because of a supposed threat to society.

111. Matesanz R. Organ and tissue trafficking. Organs and tissues 2003; 6 (2): 85-91.

112. Kadetsky, E. Guatemala inflamed. Village Voice. May 31, 1994.

113. Radford B: Kidney thieves. Times, September 2002.

114. Todd Leventhal: The child organ trafficking rumour: a modern legend. Report of the United States Information Agency, Dec, 1994.

None of these claims has ever been reported to the police or confirmed by serious evidence, even after thorough investigations by international bodies. Several investigations into these stories have failed to show that they are true. The main problem occurs when one of these myths, whatever the particular details, attracts great publicity and appears in the media or gets caught up in politics. These stories, combined with actual current trends in trafficking related to transplantation, generate a climate of distrust in the donation and transplantation system, with a resulting negative impact on much-needed altruistic donation.

Several such urban legends have emerged concerning child disappearances, especially in Latin America: for example, a young girl was said to have been kidnapped and then turned up minus her eyes but with 3 euros on her; some men dressed as clowns in a suburb claimed to have enticed children into a van where they killed them and then sold their organs.

The stories of children being kidnapped or sold to serve as organ donors have been given credence even by international organisations. A very particular example was the report prepared by an MEP in 1993, claiming that trafficking on an industrial scale had been proven. In particular, the document referred to a European country hosting 3 000 children from Latin America who had been "sent" there for that purpose. As a result, the European Parliament approved a resolution against organ trafficking, which admittedly was of great value but gave credence to the assertions made in the report without any evidence to back them up. This study had a negative impact on European public opinion, which was inclined to believe any accusation coming from such a highly regarded institution as the European Parliament.

None of these stories or any of the many other older ones reported in the medical literature,[115] has been proven to be true. Lack of evidence and simple technical arguments suffice to dismantle the stories. First, paediatric organs (in particular those from newborns, the group most frequently mentioned in the stories) are not ideal for transplantation because of a lack of maturity and/or the difficulty of finding suitable recipients for such organs in terms of size. Organs from children would be suitable for children or small adults and it is quite unusual for children to be in need of an organ. To be effective and lucrative, this kind of activity would obviously have to be targeted at adult recipients and hence based on adult donors.

Second, the process of donation and transplantation is a complex one which requires well trained professionals and sophisticated techniques to evaluate the suitability of the organs for transplantation, prepare the recipients and perform the procedure of removal and transplantation itself, while also involving preservation techniques and solutions. Afterwards, transplanted patients require the long-term use of immunosuppressive medication and also examinations and other specialised medical care. If the myth were true, it would clearly be easy to find the infrastructure behind it and traces of a huge number of transplanted patients with organs from a clandestine market of this kind.

Third, transportation of organs from one part of the world to another, which is sometimes also reported, faces the problem of long ischaemic time that would invalidate the subsequent utilisation of these organs for transplantation (a heart can barely support ischaemic times of 2-3 hours, the liver 6-7 hours).

115. Matesanz, R: Tráfico de órganos. Hechos, ficciones y rumores. Nefrología 1994: 14: 633-645.

Consequences of trafficking in OTC and trafficking in human beings for the purpose of organ removal

Trafficking and ethics

It is important to distinguish debate about the morality of markets in organs from debate about the problem of trafficking in organs and tissues and trafficking in human beings in order to obtain organs or tissues. Critics of markets in body parts maintain that they are ethically wrong because they violate a fundamental ethical norm that the body should not be treated either as property or as a commodity. Others maintain markets are ethically wrong because, if permitted, they will lead to undesirable consequences such as a fall in the overall supply of organs and tissues, skewing of the distribution of organs and tissues towards the rich, a decline in the quality of organs and tissues available because sellers are more inclined to misrepresent their health status and the inability of regulation to protect the interests of sellers.

Each of these arguments is important and may constitute a valid reason to discourage the establishment of markets in organs and tissues from living or deceased persons. However, there would seem to be further problems involved with trafficking that have not been identified or go beyond issues involving voluntary, controlled markets. The two most important moral dimensions that distinguish trafficking from controlled markets

and make trafficking, particularly trafficking in human beings for the purpose of organ removal, especially heinous are coercion and exploitation.

Every individual has the basic human right to control their own life. Respect for human dignity and autonomy implies respect for each individual's decisions. "Every human being of adult years and sound mind has the right to determine what should be done with his own body".[116] Selling one's kidney may be a reflection of 'autonomy' or free choice in academic debates about selling organs and tissues, but that is not the case when either somebody is threatened with harm unless they provide the kidney or making a kidney available is the only option available to the desperately poor.[117]

Free choice is imperilled by force. It can also be rendered irrelevant by high compensation, not because the sellers are rendered irrational by the prospect of money, but, for those in need of money, certain offers, no matter how degrading, are irresistible.[118] "Those in severe debt with no alternatives cannot truly be said to choose to become organ vendors if those to whom they are in debt force them into sales. Choices require options as well as the ability to reason about them." Poverty and dire circumstances not only interfere with an individual's autonomy but conflict with individual liberty.

Some argue that it is paternalistic to favour prohibition of organ sales:

> To prevent them making these decisions is to judge that they are unable to make a decision about what is best for their own lives.[119]

However, when an individual is coerced by threats of violence to themselves or to others they are not making choices. Nor are those for whom the sale of their bodies is the only possible option they have for earning income to maintain their very existence. Treating someone solely as a portable source of organs and tissues is both degrading to human dignity and offensive to the notion of respect for human liberty and autonomy that derives from the concept that each individual should be free to control his or her own destiny as acknowledged in United Nations and Council of Europe conventions and declarations.

Trafficking in human beings for the purpose of organ removal can thus be characterised by the presence of either the element of force or threat to obtain organs or tissues (coercion) or the taking advantage of the extremely limited choices which an individual has (exploitation). Coercion and exploitation are the moral hallmarks of trafficking in human beings for the purpose of organ removal. They are what makes this crime especially morally heinous. They are additional factors that render it unacceptable, quite apart from the moral argument that the human body should not be used solely as a commodity.

The individual consequences of trafficking

For the live donor

The impact of trafficking related to transplantation on the living donor includes medical, psychological and social problems. Concern about living donors has been reflected in the relevant consensus documents drawn up at major international conferences on establishing international standards for evaluation and care for live donors and in the development of a position of the transplantation society about the responsibility of the community for living donors. The most representative examples of such initiatives have been the Amsterdam Forum on the evaluation and care of the live kidney donor[120] and the Vancouver Forum[121] focusing on the non-kidney living donor (liver, pancreas, lung and intestine).

Even in the best-case scenarios, involving the scrupulous implementation of the recommendations made by these forums, live donation is associated with a series of complications, which have been described previously, including not only medical aspects but also psychological and social problems. Unfortunately, the consequences of live donation still need to be addressed carefully, especially in the long term. The lack of detailed information about the evolution of the live donors in this regard even in the most controlled circumstances highlights still more clearly the precariousness of living donors in many situations where the donation took place in the context of an economic transaction.

There could well be medical problems detected during the evaluation of the donor and complications related to donation that arise thereafter. It is quite unlikely for the local healthcare system to assume any responsibility for these problems and complications. So what happens with persons acting as commercial live donors who are frequently victims of trafficking in human beings?

Some studies have been published on the consequences of live kidney "donations" when the "donation" has taken place in the context of a sale or purchase. They show deterioration in the perceived health status of the donor in 58% to 86% of the cases.[122] [123] [124] Depression and anxiety

116. Scheper-Hughes, Nancy. "Bodies of Apartheid: The Ethics and Economics of Organ Transplantation in South Africa." Given 28 September 1999. Organs-Watch - University of California, Berkeley. Available: http://sunsite.berkeley.edu/biotech/organswatch/pages/bodiesapart.html. Accessed: 3 June 2008. (Hereafter "Scheper-Hughes. 'Apartheid.'").
117. Budiani-Saberi, D.A., and Delmonico, F.L. "Organ Trafficking and Transplant Tourism: A Commentary on the Global Realities." American Journal of Transplantation 2008; 8: 925-929.
118. Caplan, Arthur L. "Transplantation at Any Price?" American Journal of Transplantation 2004; 4: 1933-1934.
119. Savulescu, J. "Is the sale of body parts wrong?" Journal of Medical Ethics 2003; 29: 138-139.
120. Delmonico F; Council of the Transplantation Society. A Report of the Amsterdam Forum on the Care of the Live Kidney Donor: Data and Medical Guidelines. Transplantation 2005; 79 (6 Suppl): S53-66.
121. Pruett TL et al. The ethics statement of the Vancouver Forum on the live lung, liver, pancreas and intestine donor. Transplantation 2006; 81: 1386-1387.
122. See note 108, page 60.
123. See note 109, page 60.

have been reported. This might be facilitated by a poor baseline quality of life and increased risk of experiencing more stressful life events, as recently recognised by Iranians, emphasising the need for a proper psychological evaluation and follow-up to these cases even in this "regulated [125]market". Social isolation and stigmatisation associated with a person for having sold his kidney have also been described. Series are consistent with the fact that the main underlying motivation for donation is poverty. Donors usually live in miserable circumstances. Notably, far from being resolved, the financial problems which meant these people were forced to sell their organs are compounded when the family income drops because of the deterioration in the healthcare status of the donor, which might be more evident because of labour-intensive jobs. Most of the commercial living donors express regret for having sold a kidney and would never recommend others to do so, as acknowledged by some of the scarce available literature.

The consequences of commercial living donation seem also to reach beyond the donor, to the family and the community to which he/she belongs. "The sale of a kidney by one family member can inevitably lead to subtle and not-so-subtle pressures on others to follow suit, and it carries with it the potential for the eventual stigmatization of individuals and of whole communities as organ sellers." [126]

If the lack of evidence is a problem in the case of live donation in controlled circumstances, one can only imagine the consequences, which are merely hinted at in some of these reports, in countries where the healthcare situation is inadequate and when an economic transaction, bearing no relation to altruism or solidarity, was the reason behind the donation.

For the recipient

There are undoubtedly more abundant data series available in the literature describing the medical evolution of recipients of organs obtained in the context of a commercial transaction, usually far from the recipient's country of residence, and as part of trafficking related to transplantation. The results concerning the progress of these patients are contradictory. Some data show similar progress of these recipients compared to that of patients transplanted in their own country. In contrast, other data show lower patient and graft survivals and many studies have found a higher incidence of transplant-related complications than those described in normal conditions. These complications include the transmission of infectious diseases and the development of surgical complications.

For example, Prasad described the progress of 20 recipients who received a kidney transplant from an unrelated living donor on the basis of commercial transactions in other countries from 1998 to 2005 and returned to Canada for post-transplant follow-up care.[127] Three-year graft survival was 60%, significantly lower than that described in the centre for living donor kidney transplantation from donors with a genetic or emotional relationship with the recipient. The lack or inadequacy of documentation on relevant aspects of the transplant procedure was a common problem which complicated the management of the recipients from the medical point of view. Thirty-three percent of the patients required urgent admission to hospital on arrival, 70% developed a surgical complication and 52% a serious opportunistic infection, which included cases of active tuberculosis and fungal infections that caused the death of two patients.

More recently, a similar series was reported by the University of California, Los Angeles (UCLA), on the follow-up of 33 kidney recipients who had travelled abroad for transplantation.[128] Most of them had received their kidneys from unrelated living donors. Four patients required urgent hospitalisation immediately after presenting at UCLA, three of whom lost their grafts. Seventeen (52%) patients had infections, with nine requiring hospitalisation. One patient lost her graft and subsequently died from complications related to donor-contracted hepatitis B.

The existence of data series like this shows that when a commercial transaction is the motivation for donation, the standards in the selection and evaluation of the donor and/or the organs and the peri-operative management of the recipient would appear to be poor. However, some authors acknowledge that the frequency of the complications referred to has been declining over the years, which would suggest the gradual sophistication of the procedures in an attempt to promote an attractive image for an awful but tremendously lucrative business.

The global consequences of trafficking in OTC and trafficking in human beings for the purpose of organ removal

Organ trafficking and trafficking in human beings for the purpose of organ removal, real facts and myths, erode the image of organ donation and transplantation worldwide.[129] Data from a Spanish multi-centre national survey[130] documented a sig-

124. See note 110, page 60.
125. Quality of life and life events of living unrelated kidney donors in Iran: a multicenter study. Nejatisafa AA, Mortaz-Hedjri S, Malakoutian T, Arbabi M, Hakemi MS, Haghighi AN, Mohammadi MR, Fazel I. Transplantation. 2008 Oct 15; 86 (7): 937-40.
126. Moazam F, Zaman RM, Jafarey AM.Conversations with kidney vendors in Pakistan: an ethnographic study. Hastings Cent Rep. 2009 May-Jun; 39 (3): 29-44.
127. Prasad GV, Shukla A, Huang M, D'A Honey RJ, Zaltzman JS. Outcomes of commercial renal transplantation: a Canadian experience. Transplantation. 2006 Nov 15; 82 (9): 1130-5.
128. Gill J, Madhira BR, Gjertson D, Lipshutz G, Cecka JM, Pham PT, Wilkinson A, Bunnapradist S, Danovitch GM. Transplant tourism in the United States: a single-center experience. Clin J Am Soc Nephrol 2008; 3 (6): 1820-1828.
129. Matesanz R. Organ donation, transplantation and mass media. Transplant Proc 2003; 35: 987-989.
130. Martín A. Donación de órganos para trasplante: Aspectos psicosociales. Nefrología 1991; 11: 62-68.

nificant relationship between the degree to which the public is prepared to accept organ donation on the one hand and the belief that transplantation is a good and positive element of health care on the other. Both ordinary citizens and also health workers not specifically involved in transplantation medicine are negatively influenced by the various stories,[131] [132] which tend to create a negative atmosphere in this area. This, in turn, is an important drawback when approaching families to request organ donation or to inquire about the wishes of the deceased, one of the most sensitive moments in the process of organ donation and transplantation.[133] [134]

The mechanism behind this effect is not straightforward. Instinctively, it is easy to relate the negative impact to an increase in the rate of refusals to donate following deterioration in the image of transplantation among the general public, but the process is very frequently more complex. Instead of or in addition to the increase in refusals, there might be a decline in the detection of potential donors by the relevant physicians, possibly because they adopt a defensive position in response to public distrust of the system when any of these scandals occur.

An example of the particular impact of news about organ trafficking related to transplantation on organ donation rates occurred in Spain in 1996, in what was the largest media scandal on the subject in the country to date. One of the most prestigious awards in Spain is the "Juan Carlos I" award, which includes a prize for the best reporting by a foreign journalist at international level. In 1996, the jury made up of relevant personalities decided to confer the award on the Brazilian journalist, Beatriz Magno, for her work at the *Correio Braziliense* with a series of articles regarding organ trafficking and trafficking in humans beings for the purpose of organ removal in Latin America. The articles concerned were merely a recapitulation of all the reports on the issue which had already circulated in many countries, with just one original new version of the urban legend of stolen kidneys.

Despite the fact that the stories had not been proven and the fear expressed by the United States government about the potential danger of a prize giving credence to them, the media impact of the news was enormous and the issue of trafficking related to transplantation stayed in the media spotlight for a week. This led to a decrease, albeit limited, in the deceased donation rates in Spain. A link with negative images of transplantation, as conveyed in this case by the media on the basis of unproven stories about trafficking does therefore exist.

Detection of potential deceased organ donors and obtaining consent to proceed with organ donation are considered the two weakest links in the complex chain of the process of deceased donation.[135] A positive attitude on the part of professionals is essential and will obviously be missing if there is the slightest suspicion about criminal practices surrounding donation. Refusals to donate are one of the most serious obstacles in the process, reaching figures of well over 40% in the United States[136] and in many European countries.[137] Fears of trafficking in organs will probably be one of the reasons behind many of these refusals and negative attitudes,[138] particularly in countries traditionally pinpointed as being affected by trafficking, thereby causing additional difficulties for the development of a deceased donation programme based on the principle of altruistic donation.

Commercial living donation has been recognised to negatively impact upon the development of a deceased donation programme, which is an essential requirement to effectively deal with the shortage of organs for transplantation. Transplant tourism also undermines a country's ability to achieve self-sufficiency when providing organs for transplantation for nationals. This negative impact is also true for altruistic live donation. When there was an increase in unrelated commercial live donors in some of the affected countries, the number of donations performed between family members, predominant until that moment, simply disappeared with time.

Organ trafficking and trafficking in human beings for the purpose of organ removal, including current tragic realities and rumours surrounding the two issues, may damage the image of donation and transplantation to such an extent that they undermine public trust in the system, one of the mainstays for ensuring the success of a deceased donation and transplantation programme. These practices hinder the development and consolidation of a deceased donation programme and have a negative impact on altruistic live and deceased donation. Ultimately, this situation perpetuates one of the fundamental problems behind these practices: shortage of organs for transplantation.

131. Cuzin, B, Dubernard, JM: The media and organ shortage. In Organ Shortage: The Solutions. Ed by JL Touraine et al, Kluwer Academic Publisher, Dordrecht, 1995, p 287.
132. Matesanz, R: Tráfico de órganos. Hechos, ficciones y rumores. Nefrología 1994: 14: 633-645.
133. Miranda B, Matesanz R. International issues in transplantation. Setting the scene and flagging the urgent and controversial issues. Ann N Y Acad Sci. 1998; 862: 129-143.
134. Matesanz R, Miranda B: A decade of continuous improvement in cadaveric organ donation: The Spanish Model. Journal of Nephrology 2002: 15 (1): 22-28.
135. Matesanz R, Domínguez-Gil B. Strategies to optimise deceased organ donation. Transplant Rev 2007; 21: 177-188.
136. Sheehy E, Conrad SL, Brigham LE, Luskin R, Weber P, Eakin M, Schkade L, Hunsicker L. Estimating the number of potential organ donors in the United States. N Engl J Med 2003; 349 (7): 667-674.
137. International figures on organ donation and transplantation – 2007. Transplant Newsletter – Council of Europe 2008; 13 (1).
138. Coelho JC, Cilião C, Parolin MB et al. Opinion and knowledge of the population of a Brazilian city about organ donation and transplantation. Rev Assoc Med Bras 2007; 53 (5): 421-425.

B. Trafficking in OTC: international standards and initiatives

Several international standards and initiatives exist to tackle trafficking in OTC, having been developed in accordance with the medical advances in the field, which made trafficking in this regard a possibility and then a reality. This section summarises the main existing standards in this area. It should be noted in advance that there is no universally agreed definition of trafficking in OTC, although these practices are usually linked to violation of the principle that the human body and its parts must not give rise to financial gain, a principle of non-commercialisation that has become international legal *acquis*.

United Nations General Assembly

In Resolution 59/156 of 20 December 2004 entitled "Preventing, combating and punishing trafficking in human organs,"[139] the United Nations General Assembly deplored the commercialisation of the human body and urged the member states of the United Nations, should they ascertain that such a phenomenon exists in their country, to adopt the necessary measures to prevent, combat and punish the illicit removal of and trafficking in human organs. It encouraged the states to exchange experience in and information on preventing, combating and punishing trafficking in human organs.

As a follow-up to this resolution, the United Nations Secretary-General submitted a report to the General Assembly on preventing, combating and punishing trafficking in human organs. This report concluded that the extent of the problem of trafficking in human organs and tissues remained unclear and that the issue had not received priority attention. However, it found that human organs had become a commodity, being traded in an unfair and inequitable manner across the globe. Furthermore, the report pointed out that the absence of internationally agreed definitions and legal standards to provide a framework for co-operation in the area of combating the trafficking in human organs made it more difficult to understand and analyse the problem and its extent and to take appropriate countermeasures at the national, regional and international levels.

139. http://daccessdds.un.org/doc/UNDOC/GEN/N04/485/62/PDF/N0448562.pdf?OpenElement.

World Health Organization

Trafficking in human organs and tissues has been condemned repeatedly by the WHO. The World Health Assembly first condemned the trade for profit in human organs among living human beings as being inconsistent with the most basic human values, and contravening the Universal Declaration of Human Rights and the spirit of the WHO Constitution, in *Resolution WHA 40.13 on the development of guiding principles for human organ transplants*[140] in May 1987 and asked the Director-General to study the possibility of developing appropriate guiding principles for human organ transplants. *Resolution WHA42.5 on preventing the purchase and sale of human organs* of May 1989 condemned the purchase and sale of human organs and called on national legislators to intensify their efforts.

In 1991, the World Health Assembly, through resolution WHA44.25, endorsed a set of *Guiding Principles on Human Organ Transplantation*,[141] which had a great influence on professional codes and legislation. The

140. http://www.who.int/transplantation/en/WHA40.13.pdf; adopted by the 40th World Health Assembly in May 1987.

141. http://www.who.int/ethics/topics/transplantation_guiding_principles/en/.

Guiding Principles prohibit giving and receiving money and any other commercial transactions in this field, but do not affect payment of expenditures incurred in organ recovery, preservation and supply. Particular attention is paid to the protection of minors and other vulnerable individuals from coercion and improper inducement to donate organs.

According to Guiding Principle 1, organs may be removed from the bodies of deceased persons for the purpose of transplantation if **consents** required by law are **obtained and** there is **no reason to believe that the deceased person objected** to such removal, in the absence of any formal consent given during the person's lifetime.

The WHA thereby gives precedence to the principle that free and informed consent is the ethical cornerstone of all medical interventions. National legislation has to define the prerequisites for obtaining consent. Irrespective of whether an "opt-in" or "opt-out" system is implemented, any statement or indication of objection or refusal by individuals regarding the removal of organs after their death prevents any such removal.

Although express consent is not required in an "opt-out" system, institutions may be reluctant to remove organs or tissues if the relatives oppose the donation, even if national legislation does not require the relatives' consent. Alongside psychological issues involving the relatives, it should be borne in mind that it is the will of the deceased that prevails over that of his or her relatives. If permission is not sought from relatives, donor programmes should review the deceased's medical history with them to increase the safety of transplantation.

Guiding Principle 2 provides that **physicians determining the death** of a potential donor should **not be directly involved** in organ removal from the donor and subsequent transplantation procedures, or be responsible for the care of potential recipients of such organs so as to prevent any conflicts of interest.

Guiding Principle 3 stresses that **organs should be removed preferably from the bodies of deceased persons**. Donations from adult living persons are deemed permissible, but preference is given to such donors being genetically related to the recipients – except for transplantation of bone marrow and other acceptable regenerative tissues. As a major rule, Guiding Principle 3, paragraph 2, seeks to protect donors from any undue influence and pressure and requires that **adult living donors** give their **free consent** to organ removal and are **sufficiently informed** to be able to understand and weigh the risks, benefits and consequences of consent.

Guiding Principle 4 **prohibits the removal of organs from living minors** for the purpose of transplantation. However, exceptions are deemed permissible under national law in the case of regenerative tissues. According to the commentary, in such cases, the protection of minors could be assured by e.g. requiring the consent of the minor and of the parent(s) or the legal guardian. In the case of a conflict of interest on their part, prior permission of an independent body should be required, but in any case, an objection by the minor should prevail over any other consent.

According to Guiding Principle 5, the **human body and its parts must not be the subject of commercial transactions**; giving or receiving payments (including any other compensation or reward) for organs should be prohibited. This is the central provision for prohibiting traffic in human organs for payment. The commentaries clarify that the choice of methods, including sanctions, is left to states and that no payment of reasonable expenses incurred in donation, recovery, preservation and supply of organs for transplantation is prevented.

Guiding Principle 6 **prohibits commercial advertisements** of the need for or availability of organs; the promotion of altruistic donations is not, however, prohibited.

According to Guiding Principle 7, the **involvement of physicians** and other health professionals in organ transplantation procedures (including removal and implantation) should be prohibited if they have reason to believe that the organs concerned have been the subject of commercial transactions.

This principle is reinforced by Guiding Principle 8, which **prohibits** any person or facility involved in organ transplantation procedures, i.e. doctors, health practitioners and hospital staff, as well as medical centres, from receiving any **payment that exceeds a justifiable fee** for the services rendered. Consequently, those persons and institutions are not asked to offer their services for free but, on the other hand, should not make profits out of these activities and should receive only justifiable fees for their services.

Lastly, Guiding Principle 9 provides that **donated organs** should be made **available** to patients **solely on the basis of medical need** and not because of financial or other considerations.

In Resolution *WHA57.18 on Human Organ and Tissue Transplantation* adopted in May 2004, the 57th World Health Assembly requested the Director-General to update the Guiding Principles, to protect the poorest and vulnerable groups from "transplant tourism" and to pay attention to the sale of tissues and organs, including the international trafficking in human tissues and organs.

In October 2006 at the 58th WMA General Assembly, the *World Medical Association Statement on Human Organ Donation and Transplantation*, which had been adopted by the 52nd WMA General Assembly in October 2000, was revised. The WMA reiterated the universal principle of non-commercialisation of organ trans-

plants in paragraph 30, in which it pointed out that financial incentives compromise the voluntariness of the choice and the altruistic basis for organ donation and that access to needed medical treatment based on ability to pay is inconsistent with the principles of justice. The statement further provides that organs suspected to have been obtained through commercial transactions must not be accepted for transplantation. Reasonable reimbursement of expenses, e.g. those incurred in procurement, transport, processing, preservation and implantation is permissible. Commercial advertisement of organs, however, should be prohibited. Moreover, physicians asked to transplant an organ that has been obtained through a commercial transaction should refuse to do so and explain that this would be unethical.

At its 123rd session on 26 May 2008, the WHO Executive Board took note of the *Revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation,*[142] which are expected to be adopted in 2010. In terms of major changes, the following should be pointed out:

In the commentary on Guiding Principle 3, the WHA takes note that genetic or legal relationships between donor and recipient may be therapeutically advantageous, but that some donations by unrelated donors – though they have been a source of concern – are unexceptionable and that many altruistic donations also originate from emotionally related donors. However, with live donation, particularly by unrelated donors, psychosocial evaluation of the motivation and expectations regarding outcomes may help identify forced or paid donations.

Furthermore, Guiding Principle 3, paragraph 2, is extended insofar as **basic prerequisites for the acceptability of live donations** are specified, namely: obtainment of the donor's informed and voluntary consent, professional care of donors, proper organisation of follow-up and scrupulous application and monitoring of selection criteria for donors. These requirements, together with the obligation to inform living donors of the probable risks, benefits and consequences of donation in a complete and understandable fashion and for them to be competent and capable of weighing the information, stress the importance of protecting the health of living donors.

Guiding Principle 4 further provides that specific measures should be in place to protect minors and legally incompetent persons and that, wherever possible, their assent should be obtained before donation.

The principle of non-commercialisation in Guiding Principle 5 is set out in much more detail. The provision calls for an explicit ban on purchasing, or offering to purchase, cells, tissues or organs for transplantation and on their sale, and states that they should only be donated freely, without any monetary payment or other reward of monetary value. However, reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation is explicitly excluded from this ban.

This provision bears in mind that recipients may provide donors with tokens of gratitude that cannot be assigned a value in monetary terms, while stressing that national legislation should ensure that any gifts or rewards are not disguised forms of payment. However, **compensation for the costs of making donations is permitted, as is payment of legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation**. The commentary specifically underlines that the ban on commercial transactions also refers to transplant tourism.

Guiding Principle 6 is more detailed and aims at prohibiting commercial solicitations, including offers to pay individuals, the next of kin of deceased persons or other parties for cells, tissues or organs, and thereby targets brokers and other intermediaries as well as direct purchasers.

In the commentary on Guiding Principle 7, the WHA takes note of the situation physicians may find themselves in when confronted with patients willing to pay for cells, tissues or organs either before or after the intervention in the course of follow-up treatment. It states that physicians and healthcare facilities should not refer patients to transplant facilities – either in their own countries or abroad – which make use of the commercial obtainment of cells, tissues or organs, or seek or accept payment for doing so. As for post-transplant care, they are permitted to provide it to patients who have undergone transplantation at such facilities, but should not face professional sanctions if they decline to provide such care, provided they refer such patients elsewhere.

Guiding Principle 9 is supplemented by the requirement that allocation rules should be defined by appropriately constituted committees and be equitable, externally justified and transparent, whereby transparency should be central to all aspects of transplantation.

Two new guiding principles are added:

Guiding Principle 10 underlines that **high-quality, safe and efficacious procedures** are essential for donors and recipients alike and that the long-term outcomes of donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm. They are also essential to the consent process and for adequately balancing the interests of donors and recipients. The implementation of quality systems, including **traceability and vigi-**

142. http://www.eurotransplant.nl/?id=newsdetail&newsid=684.

lance, with adverse events and reactions reported, is also required in order to maintain and optimise the level of safety, efficacy and quality of human cells, tissues and organs for transplantation on an ongoing basis. Guiding Principle 11 requires that the organisation and execution of donation and transplantation activities, as well as their clinical results, are transparent and open to scrutiny, while the personal **anonymity and privacy** of donors and recipients are always protected.

These updated Guiding Principles – once adopted – will provide for the most up-to-date and comprehensive regulation of transplantations and thereby constitute an effective tool for preventing trafficking in organs and tissues if they are implemented.

Council of Europe

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (CETS No. 186)

Article 22 of the Additional Protocol expressly prohibits organ and tissue trafficking, which are key examples of making financial gain from the human body or its parts. In addition, organ and tissue trafficking infringe human rights, exploit vulnerable persons and undermine public trust in the official transplant system.

Parliamentary Assembly Recommendation 1611 (2003) on trafficking in organs in Europe

Following the *questionnaire of the Secretary General of the Council of Europe for member states on organ trafficking*, including legal and practical aspects relevant to transplantations and trafficking in organs, issued in May 2002 and the publication of the analysis of the replies of 40 European states in a report by the Steering Committee on Bioethics in 2004,[143] further action was taken by the Council of Europe Parliamentary Assembly.

The Parliamentary Assembly pointed out in its *report on "Trafficking in organs in Europe"* (Rapporteur: Ms Ruth-Gaby Vermot-Mangold) of 3 June 2003 that international criminal organisations had identified the lucrative "gap" between organ supply and demand, putting more pressure on people in extreme poverty to resort to selling their organs, and expressly disapproved of trends towards less restrictive laws, which would allow greater scope for unrelated living donation. The report drew attention to the fact that while member states legally prohibited organ trafficking, most countries still had legislative loopholes. It stated that organ trafficking should not remain the sole responsibility of so-called "donor countries" in Eastern Europe and recommended a number of measures to be taken in "donor" and in "demand" countries to minimise the risk of organ trafficking in Europe.

The report was the basis for *Recommendation 1611 (2003) on trafficking in organs in Europe,* which was adopted by the Council of Europe Parliamentary Assembly on 25 June 2003.

In the recommendation, all states were called on to implement measures to reduce demand, promote organ donation, maintain strict legislation in regard to live unrelated donors, guarantee the transparency of national registers and waiting lists, establish the legal responsibility of the medical profession and share information. The Parliamentary Assembly therefore recommended that states clearly establish criminal responsibility for organ trade in their national criminal codes, which should include brokers, intermediaries, hospital/nursing staff and medical laboratory technicians involved in the illegal transplant procedure, as well as medical staff who encourage and provide information on "transplant tourism" or are involved in follow-up care of patients who have purchased organs if they fail to alert the health authorities. However, the report expressly stated that paid donors should not be held criminally responsible insofar as most sell their organs because of their poor economic situation or because they are deceived into doing so.

The Parliamentary Assembly called on the Council of Europe to consider drafting an additional protocol to the Council of Europe Anti-Trafficking Convention which was under debate at that time. It also recommended that all member states sign and ratify the main international legal instruments in this field, namely the *Convention on Human Rights and Biomedicine* and its *Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin*, the *UN Convention against Transnational Organized Crime* and its *Protocol to Prevent, Suppress and Punish the Trafficking of Persons, Especially Women and Children*, and the *Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography*. Member states were further called on to strengthen existing mechanisms of co-operation at Council of Europe level (SP-CTO), improve funding for assistance activities, adopt and apply the recommendations adopted by the 52nd WMA General Assembly and intensify their co-operation under the auspices of Interpol and Europol.

In addition to those recommendations to all states, the report contained recommendations specifically targeted at "donor" and "demand" countries:

143. Document CDBI/INF (2003) 11 rev. 2 of 2 June 2004; http://www.coe.int/t/dg3/health/Source/CDBI_INF(2003)11_en.pdf.

Specific measures recommended for "donor countries" were the improvement of prevention (through awareness-raising and peer education) and primary healthcare, as well as steps towards identification of illegal donors, identification of potential victims and the strengthening of transplant systems. Moreover, these states were called on to restrict the donation of organs and tissues from prisoners and other individuals in custody (with the exception of donations for members of their immediate family), and implement national poverty-reduction strategies. With regard to law enforcement, donor countries were urged to include specific provisions on organ trafficking in their criminal codes and undertake effective measures to combat trafficking in organs, including the implementation of national anti-corruption programmes.

Similarly, "demand countries" were called upon to maintain strict laws in regard to transplantation from unrelated living donors and to introduce in their criminal law sanctions for medical staff involved in carrying out operations resulting from organ trafficking. It was further stated that national medical insurance should deny reimbursements for illegal transplants abroad and for follow-up care of illicit transplants, donor awareness should be improved and strict control and transparency of organ registers and waiting lists should be established, along with clear responsibilities. Data should be harmonised, "broker" advertising tracked down and necessary support provided to Interpol and Europol. It was also recommended that co-operation measures be strengthened and expertise provided to "donor" countries.

With regard to professional ethics, the report drew attention to the World Medical Association statement on human organ and tissue donation and transplantation and the Bellagio Task Force report on transplantation, bodily integrity and the international traffic in organs.

Committee of Ministers Recommendation (2004) 7 to member states on organ trafficking

Also at the Council of Europe, the Committee of Ministers on 19 May 2004 adopted *Recommendation (2004) 7 of the Committee of Ministers to member states on organ trafficking*, which took account of *Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances*, the final text of the *3rd Conference of European Health Ministers* (Paris, 16-17 November 1987), and the *World Health Organization Resolution WHA 42.5* condemning the purchase and sale of organs of human origin, as well as the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*. It applies to all living persons and to the removal of organs, tissues and cells (including haematopoietic stem cells) from those recently deceased.

The objective of the recommendation (Article 1) is to protect the dignity and identity of all persons and guarantee without discrimination their fundamental rights and freedoms with regard to organ and tissue transplantation. It expressly states that organ trafficking exploits human beings and is illegal, and that member states should take all possible measures to prevent it. The scope is broad, covering the removal of organs, tissues and cells, including haematopoietic stem cells, from living and recently deceased persons. Blood and blood derivatives are excluded. Besides definitions of the terms transplantation and removal, the main value of the recommendation is a definition of the term "**organ and tissue trafficking**". Although it groups issues of trafficking in organs together with those of trafficking in human beings for organ removal, it is still an advance, as no worldwide definition of the term exists to date. According to Article 2 (4), organ and tissue trafficking encompasses:

- the transportation of a person to a place for the removal of organs or tissues without his or her valid consent;
- the transportation of a person to a place for the removal of organs or tissues with his or her consent but in contravention of legislation or other controls in operation in the relevant jurisdiction; and
- the transplantation of removed organs and tissues, whether transported or not, in contravention of legislation or other regulations in operation in the relevant jurisdiction or in contravention of international legal instruments.

Article 2 (5) defines the term "**transplantation**", which covers the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation, storage and transportation, as well as the term "**removal**", which refers to removal from the body of an organ or tissue intended for transplantation, by a surgical procedure or by other means.

According to Article 3, prevention of organ trafficking should be undertaken in an integrated way by improving organ and tissue availability and approving a legal framework which strictly forbids any kind of commercialisation of the human body and its parts, which should be extended to include citizens going abroad.

Regarding medical aspects, it recommends that medical care should not be denied and that the traceability of human organs and tissues should be assured through the accreditation and control of centres for procurement and/or transplantation, tissue banks and the follow-up of patients. In the case of a living donor transplant, member states should provide for official authorisation of all such transplants and all payments to the donor

should be strictly prohibited and considered a criminal offence. While clearly reaffirming the principle that all payments to living donors should be strictly prohibited, the recommendation provides that this should not apply to **payments which do not constitute a financial gain or a comparable advantage**, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation; and
- compensation in case of unjustified harm resulting from the removal of organs or tissues from living donors.

To avoid illegal transactions, it is recommended that in cases where the living donor is a foreign citizen, the relevant officially recognised bodies in the country of transplantation and in the home country of the living donor must be informed.

According to Article 4, states should ensure that there are legal instruments in place which prohibit the trafficking of persons for the purpose of organ or tissue transplantation and the trafficking of organs and tissues themselves and that these instruments prohibit:

- the removal and the implantation of organs and tissues except in centres or circumstances recognised for the purpose and by health professionals with appropriate training and experience,
- financial gain from the human body or parts of the body intended for transplantation,
- advertising with the intention of securing persons or organs or tissues for trafficking or for financial gain; and organising or running an organisation or service involved in organ or tissue trafficking.

Member states should establish **transplantation systems guaranteeing equitable access to transplantation services** and **national transplant waiting lists** (Article 5). In any case, the system must ensure that appropriate information is recorded on all organs and tissues removed and used in connection with transplantation, that they are only allocated to persons who are on a nationally recognised waiting list and that information on the risks associated with organs obtained illegally is provided. The information should ensure traceability from donor to recipient, but data protection must be observed.

As organ trafficking is a universal problem, the recommendation draws attention to the need for full co-operation with all other states and with international agencies (Article 6). Moreover, the general public should be informed about organ trafficking and the penalties that may be incurred, while organ and tissue donation and transplantation should also be promoted as positive behaviour that contributes to saving lives and improving the health of many people (Article 7).

Committee of Ministers Resolutions (2008) 4 on adult-to-adult living donor liver transplantation and (2008) 6 on transplantation of kidneys from living donors who are not genetically related to the recipient

Both *Resolutions CM/Res (2008) 4 on adult-to-adult living donor liver transplantation* and *CM/Res (2008) 6 on transplantation of kidneys from living donors who are not genetically related to the recipient* are linked to the issue of trafficking in organs. They provide that organ removals may be envisaged when suitable organs from deceased donors are not available, provided that all safeguards are implemented in order to guarantee the freedom and safety of the donor and a successful transplant in the recipient, and stress that no organ removal may be carried out on a person who does not have the capacity to consent.

European Union

Trafficking in organs has not been included in the scope of relevant EU instruments. The three most closely related instruments, namely the *Council Framework Decision of 19 July 2002 on combating trafficking in human beings* (OJ L 203, 1.8.2003), *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells* (OJ L 102, 7.4.2004) and *Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells* (OJ L 38/40, 9.2.2006) do not cover the issue of trafficking in organs.

The definition of trafficking in human beings in the *Council Framework Decision of 19 July 2002 on combating trafficking in human beings* basically refers to the definition of the United Nations Trafficking in Persons Protocol, but differs from it in certain respects, most importantly in its scope, as the Framework Decision covers only the purposes of sexual and labour exploitation and not exploitation for organ removal.

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells recognised the fact

that the use of organs to some extent raises the same issues as the use of tissues and cells, but nevertheless decided that the two subjects should not be covered by the same instrument because of the differences.[144] It did not therefore include human organs, blood or blood products.

Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues

As trafficking in organs was not addressed by these EU instruments, Greece in 2003 presented the *Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues,*[145] which took account of the facts that removal of human organs and tissues is a form of exploitation of human beings and that the legislation in the member states differs substantially regarding the definition of the penalties.

Article 1 of the initiative sets out definitions of transplantation and tissues and provides that the scope of human organs and tissues does not cover reproductive organs and tissues,[146] embryonic organs and tissues[147] or blood and blood derivatives.[148]
Article 2 describes a whole range of acts that should be punished as offences constituting trafficking in human organs and tissues:

> **Article 2**
> **Offences concerning trafficking in human organs**
>
> Each member state shall take the necessary measures to ensure that the following acts are punishable:
>
> 1. The recruitment, transportation, transfer, harbouring or reception of a person, including any exchange or transfer of control over that person, where
>
> a. use is made of force or threats, including abduction; or
>
> b. use is made of fraudulent means; or
>
> c. there is an abuse of authority or of a position of vulnerability which is such that the person concerned has no real or reasonable possibility of avoiding such abuse; or
>
> d. payments or benefits are given or received in order to obtain the consent of a person having control over another person with the aim of removal of an organ or tissues from the latter.
>
> 2.a. the removal of an organ from a living donor effected using force, threats or fraud;
>
> b. the removal of an organ from a donor who has consented thereto further to the payment or promise of financial consideration;
>
> c. the payment, offer or promise of a financial consideration, directly or via third parties, to a donor in order to obtain his consent to the removal of an organ;
>
> d. the receipt of or demand for financial consideration by a donor or a third party so that the donor will agree to the removal of an organ;
>
> e. action as an intermediary in carrying out any of the acts set out in points (a), (b), (c) and (d);
>
> f. the demand for, receipt, payment, offer or promise of financial consideration with the aim of offering or acquiring or, more generally, trafficking in human organs and tissues.
>
> 3.a. the purchase, possession, storage, transport, import, export or transfer of possession of human organs removed by means of one of the acts set out in paragraphs 1 and 2;
>
> b. participation by medical or nursing staff in the transplantation of an organ in the knowledge that it has been the object of one of the above-mentioned acts.

Article 2 (1) is similarly structured to the offences in the Council Framework Decision of 19 June 2002 (which is limited to sexual and labour exploitation), whereas Article 2 (2) and (3) reflect specific features and issues related to trafficking in human organs.

The punishment of instigation, aiding and abetting are required by Article 3. Effective, proportionate and dissuasive criminal penalties which may constitute the basis for extradition are provided for in Article 4. The penalties must be increased in cases of aggravating circumstances. These provisions are supplemented by provisions on the liability of legal persons (Articles 5 and 6) and jurisdiction and prosecution (Article 7). Jurisdiction is extended to cases where the crime is committed outside national territory, thereby specifically including jurisdiction for cases of "transplant tourism", i.e. travel by EU citizens to countries with lower standards to avoid the strict legislation in EU member states.

Pursuant to Article 39 (1) of the EC Treaty, the Council consulted the European Parliament on this initiative. The Committee on Citizens' Freedoms and Rights, Justice and Home Affairs adopted a draft legislative resolution on the initiative on 30 September 2003. The European Parliament[149] approved the amended version of the Initiative of the Hellenic Republic and called on the Council to alter its proposal accordingly. It also insisted that the Council refrain from adopting the framework decision prior to the adoption of the *European Parliament and Council Directive on human tissues and cells*. The Parliament proposed the fol-

144. Directive 2004/23/EC, Recital 9.
145. OJ C 100, 26.4.2003, p. 27.
146. Article 1 (3) (a).
147. Article 1 (3) (b).
148. Article 1 (3) (c).

149. Draft European Parliament legislative resolution on the Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues (7247/2003 – C5-0166/2003 – 2003/0812 (CNS)).

lowing major amendments in particular:

The European Parliament (EP) proposed that the term "trafficking in human organs" be changed to "illegal trafficking in human organs, parts of organs and tissues",[150] as the original title was "ambiguous in its reference to 'trafficking', which can imply both legal and illegal trade. It is necessary to acknowledge that a legitimate and regulated trade exists for medical purposes, such as fertility treatment".[151] The Parliament further stated that "(i) Illegal trade in human organs should be understood as the conscious engagement and participation in any form in provision, acquisition or use of human organs that breaches the conditions for legal transplantation."[152] It also argued that it was necessary to look for alternatives aiming to end the shortage of donated cells, tissues and organs.[153]

Furthermore the EP proposed the deletion of Article 1 (3), which limited the scope of the term "human organs and tissues" to be covered by the instrument[154], underlining that the scope needed to be extended, as the aim must be to combat illegal trafficking in all circumstances.[155] The EP made it clear that it did not seek to prohibit legal trade in reproductive organs and tissues, but to criminalise such trade where it takes place outside the legal regulatory framework for the relevant activities.

It also took note of the fact that there is evidence that a growing number of EU nationals, desperate for a transplant, are entering into commercial transactions with a person in another country where payment is not unlawful. It therefore proposed

> to reorder the definition of offences set out in Article 2 into three broad categories:[156]
>
> 1. Trafficking in human beings for the purpose of organ and tissue removal;
>
> 2. Commercial dealings in human organs and tissues; and
>
> 3. The removal of organs by force, coercion and deception.

The EP also proposed that the provision of comparable advantages should be regarded as equivalent to the payment of a financial consideration so that the ban on organ trafficking would not be too easily circumvented.[157]

Additionally, it said that the provision which would make living donors criminally responsible for selling, or offering to sell their organs[158] should be removed, as it "does not seem appropriate to criminalise a donor, who, in the vast majority of cases, will have been persuaded or coerced by criminal networks in the hope of escaping from extreme poverty."[159] The main aim of the initiative should be to tackle the agents of the illegal trafficking in human organs, not to exacerbate the suffering of its victims.[160]

In line with Article 21 (2) of the *Additional Protocol to the Convention on the Transplantation of Organs and Tissues of Human Origin*, the European Parliament proposed the punishment of anyone who advertises, "via the Internet or any other medium, the need for, or availability of, organs, parts of organs or tissues, with a view to offering or seeking financial gain or comparable advantage".[161]

On the other hand, it also wanted to make sure that payments to donors which do not constitute a financial gain or a comparable advantage are not prevented,

> in particular:
>
> – compensation of living donors for loss of earning and any other justifiable expenses caused by the legal removal or by the related medical examinations;
>
> – payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;
>
> – compensation in case of undue damage resulting from the legal removal of organs, part of organs or tissues from living persons.[162]

In addition, it proposed that donors be allowed to receive compensation so that they agree to the removal of an organ[163] and justified this amendment as follows:

> The fact that the human body should not be a source of profit is at the very core of this proposal. However, as already laid out in the *Additional Protocol to the Convention on the Transplantation of Organs and Tissues of Human Origin*, this should not prevent voluntary donors from being offered reasonable compensation, such as for loss of earnings and travel costs.[164]

According to this provision,

> organs, parts of organs or tissues should not be bought or sold or give rise to direct financial gain for the person from whom they have been removed for a third party. Nor should the person from whom they have been removed, or a third party, gain any other advantage whatsoever comparable to a financial gain, such as benefits in kind or promotion. A third party involved in the transplant process, such as a health professional or a tissue bank,

150. Amendment 1 (throughout the text and in the title).
151. Draft European Parliament legislative resolution on the Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues (7247/2003 – C5-0166/2003 – 2003/0812 (CNS)); in the following: Draft European Parliament legislative resolution; explanatory statement, page 26.
152. Draft European Parliament legislative resolution; Justification regarding amendment 1.
153. Draft European Parliament legislative resolution; Justification regarding amendment 4.
154. Amendments 19 to 22 (regarding Article 1 (3)).
155. See: Draft European Parliament legislative resolution; Justification regarding amendment 19.
156. Draft European Parliament legislative resolution; explanatory statement, page 28.
157. Amendment 30 (regarding Article 2 (2) (c)).
158. Amendment 31 (regarding Article 2 (2) (d)).
159. Draft European Parliament legislative resolution; explanatory statement, page 28.
160. Draft European Parliament legislative resolution; Justification regarding amendment 31.
161. Amendment 34 (regarding Article 2 (2) (fa) (new)).
162. Justification regarding Amendment 35 (regarding Art 2 (2b) (new)).
163. Amendment 35 (regarding Article 2 (2b) (new)).
164. Draft European Parliament legislative resolution; explanatory statement, page 28.

> may not make a profit from organs, part of organs or tissues or any products developed from them.[165]

This proposed paragraph was not meant to create any exception to the principle laid down, but to give

> examples of compensation to avoid possible financial disadvantage which may otherwise occur that are not to be treated as financial gain or comparable advantage.[166]

The draft framework decision was discussed in the Working Party on Substantive Criminal Law of the Council of the European Union from February 2003, with several delegations requesting from the outset that the experts who were at that time examining a draft directive on the quality of tissues be involved in the discussions. Several EU member states raised reservations regarding the text and the need for the instrument, arguing that in most member states no cases of trafficking in organs were known. It was also pointed out that the outcome of a study under the Falcone Programme should be awaited as a more substantial basis for the discussions. Accordingly, as the initiative had not received sufficient support from delegations, the discussions on the initiative were suspended, pending further detailed information on the situation in the European Union.

Motion for a European Parliament Resolution on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI))

The European Parliament in 2007 launched a new initiative for action in the field of organ trafficking, the *Motion for a European Parliament Resolution on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI))*.

A specific chapter deals with organ trafficking. The EP highlighted the link between organ shortage and organ trafficking, stating that organ trafficking undermines the credibility of the system for potential voluntary and unpaid donors and emphasised that any commercial exploitation of organs is unethical and inconsistent with the most basic human values.[167] It asked the Commission to fight against the practice of organ and tissue trafficking, including the transplantation of organs and tissues from minors, from the mentally disabled or from executed prisoners[168] and called on the Commission and member states to take measures to prevent "transplant tourism" by drawing up guidelines to protect the poorest and most vulnerable donors from being victims of organ trafficking, adopting measures that increase the availability of legally procured organs and by exchange of waiting list registrations between existing organ exchange organisations to avoid multiple listing.

In addition, it asked the Commission to promote a common approach which aims at compiling information on national organ trafficking legislation and to identify the main problems and potential solutions.[169] Member states were urged, where necessary, to amend their criminal codes to ensure that those responsible for organ trafficking are adequately prosecuted, including sanctions for medical staff involved in transplantation of organs obtained from trafficking, while making every effort to discourage potential recipients from seeking trafficked organs and tissues; this should include consideration of criminal liability of European citizens who have purchased organs inside or outside the EU.[170]

Lastly, member states were called on to take the necessary steps to prevent healthcare professionals from facilitating organ and tissue trafficking as well as health insurance providers from facilitating activities that directly or indirectly promote trafficking in organs[171] and to sign, ratify and implement the Council of Europe Anti-Trafficking Convention and the United Nations Trafficking in Persons Protocol if they have not already done so.[172]

The members of the European Parliament regretted that Europol had not come up with a survey on organ selling and trafficking because it claims that there are no documented cases. Referring to reports of the Council of Europe and WHO which give evidence that the organ trade is also a problem for EU member states, the members of the EP asked the Commission and Europol to improve monitoring of cases of organ trafficking.

165. Draft European Parliament legislative resolution; Justification regarding amendment 35.
166. Draft European Parliament legislative resolution; Justification regarding amendment 35.
167. Motion for a European Parliament Resolution on organ donation and transplantation, para 49.
168. Motion for a European Parliament Resolution on organ donation and transplantation, para 50.
169. Motion for a European Parliament Resolution on organ donation and transplantation, para 52.
170. Motion for a European Parliament Resolution on organ donation and transplantation, para 53.
171. Motion for a European Parliament Resolution on organ donation and transplantation, para 54.
172. Motion for a European Parliament Resolution on organ donation and transplantation, para 55.

The Iberoamerican Network/Council of Donation and Transplantation (RCIDT)

The RCIDT Declaration against transplant tourism in Latin America[173] was adopted recently. It is based on the WHO guiding principles on donation and transplantation (especially Guiding Principles 5, 6, 7 and 8) and the RCIDT statements on bioethical

173. http://www.grupopuntacana.org/materiales_consejo/declaraturismotraspla.pdf.

considerations. The document was drawn up because some Latin American countries have been pinpointed as places where practices such as transplant tourism, deceptive publicity and organ commercialisation occur.

In the declaration, the RCIDT voices its concern about the confirmation of transplant tourism in some Latin American countries and expresses its opposition to and disapproval of the practice. In addition, it recommends that governments of member states oppose and/or take measures in their legislation to control and sanction the promotion of and publicity for transplant tourism, "as these practices promote inequity, exclusion and social injustice, and violate human rights of national recipients". It indicates that it will give support "to move forward the identification of promoters and sponsors of transplant tourism that is detrimental to the citizens of the country where the transplant is performed, and distorts the general activity [i]n donation and transplantation of the entire region". It also states that all citizens of countries in the network who need a transplant must be able to access the latter in a manner characterised by transparency, efficiency and quality, through their own actions or through co-operation agreements that are fair, equitable and involve solidarity between the countries in the network, giving priority to transplantation for those in need with organs from donors from their own country.

The Transplantation Society and the International Society of Nephrology

At the International Summit on Transplant Tourism and Organ Trafficking held by the Transplantation Society and the International Society of Nephrology from 30 April to 2 May 2008, the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* was adopted. The declaration points out that all countries need a legal and professional framework to govern organ donation and transplantation activities, as well as a transparent regulatory oversight system that ensures donor and recipient safety and the enforcement of standards and prohibitions on unethical practices, which are partly an undesirable consequence of the global shortage of organs for transplantation. It recommends that all countries should implement measures to meet the transplant needs of their residents from donors within their own population or through regional co-operation and that the therapeutic potential of deceased organ donation should be maximised.

Principle 6 underlines that organ trafficking and transplant tourism violate the principles of equity, justice and respect for human dignity and should therefore be prohibited. It accordingly recommends that prohibitions on these practices should include a ban on all types of advertising (including electronic and print media), soliciting or brokering for the purpose of transplant commercialism, organ trafficking or transplant tourism and that such prohibitions should also include penalties for acts (such as medically screening donors or organs, or transplanting organs) that aid, encourage or use the products of organ trafficking or transplant tourism. Furthermore, it states that practices that induce vulnerable individuals or groups (such as illiterate and impoverished persons, undocumented immigrants, prisoners and political or economic refugees) to become living donors are incompatible with the aim of combating organ trafficking, transplant tourism and transplant commercialism.

Consistent with the principles in this declaration, several strategies to increase the donor pool and to prevent organ trafficking, transplant commercialism and transplant tourism and to encourage legitimate, life-saving transplantation programmes are suggested. Their aims are especially to increase deceased organ donation and to ensure the protection and safety of living donors and appropriate recognition for their heroic act while combating transplant tourism, organ trafficking and transplant commercialism. In particular, it is recommended that the medical and psychosocial suitability of the living donor should be determined according to the recommendations of the Amsterdam and Vancouver Forums, and that systems and structures should ensure standardisation, transparency and accountability of support for donation. The care of organ donors, including those who have been victims of organ trafficking, transplant commercialism and transplant tourism, is said to be a critical responsibility of all jurisdictions that sanctioned organ transplants utilising such practices.

It is also pointed out that provision of care includes medical and psychosocial care at the time of donation and for any short- and long-term consequences related to organ donation. Lastly, the importance of comprehensive reimbursement of the actual, documented costs of donating an organ is mentioned, which does not constitute a payment for an organ, but is part of the legitimate costs of the recipient's treatment.

Asian Task Force on Organ Trafficking

In January 2008, the members of the Asian Task Force on Organ Trafficking issued the *Recommendations on the Prohibition, Prevention and Elimination of Organ Trafficking in Asia (Taipei Recommendations)*.[174] These are based upon "persistent reports of unethical and unjust practices relating to the transplant of organs in Asia involving citizens of the region as well as those of other parts of the world" and "worldwide reports on the exploitation of poor and other vulnerable individuals as organ donors".

In addition to listing several aspects of organ trafficking and making reference to ethical principles set out in international documents and declarations, the text formulates several recommendations regarding trafficking in human organs. However, the recommendations might also be considered with regard to trafficking in tissues and cells.

In the recommendations, relevant organisations and governments are urged to promote greater awareness of the ethical, legal and social issues relating to organ trafficking in Asia through education. With respect to legislation, international legal action is advocated for the effective implementation of international norms that relate to organ trafficking, as is national legislation clearly defining prohibitions as well as allowable practices pertaining to organ transplantation, including those related to the recovery and donation of organs. To increase the supply of organs, Asian countries are urged to rely more on deceased donation and to identify alternative solutions in order to decrease organ demand, such as prevention and treatment of organ failure. Recommendations to address prevention, assistance (e.g. involvement of civil society, ensuring the physical and psychological health of live organ donors by providing counselling and supports) and monitoring measures are also part of the document. In addition, organisational issues are addressed, *inter alia* in the recommendations urging Asian countries to achieve national self-sufficiency in order to provide a sufficient number of organs for their residents who need transplantation and to establish registries of transplant recipients and waiting lists, as well as registries of living donors. Exchanges of information and technical experience as well as scientific research are also recommended.

The document is comprehensive and also covers important technical-organisational aspects, calling on countries to observe transparency and accountability in regulations and practices, adopt policies to discourage citizens from transplantation tourism and consider a reasonable and socially accepted cost reimbursement as compensation for altruistic living organ donors, while urging insurance companies to abstain from policies with the effect of supporting illegal practices in organ transplantation.

174. http://www.law.ntu.edu.tw/center/wto/04research.asp?tb_index=403.

C. Trafficking in human beings: international standards and their application to organ removal

This section will focus on existing international standards dealing with trafficking in human beings for the purpose of organ removal and seek to differentiate the latter from organ trafficking, as previously addressed.
Trafficking in human beings seems to be a very modern and new topic. But in the international context, trafficking in human beings and slavery have a very long history: we only need to think here of the consequences of the Spanish Conquest in America, events in other former European colonies, the African slave trade or certain large-scale construction projects. Legal initiatives also started more than a century ago.
In the past, however, trafficking in human beings was not understood in the same comprehensive way as it is nowadays, and legal instruments did not deal with all its forms from the very beginning. The early instruments focused on specific aspects of trafficking in human beings, namely sexual and labour exploitation. Trafficking in human beings for the purpose of organ removal, as a very modern development, was only included in international measures this century. However, the early instruments laid the foundations for modern legislation and provided the basis for the legal framework for national and international action in cases of trafficking in human beings for the purpose of organ removal. This section describes the international legal instruments which deal specifically with trafficking in human beings and their application to organ removal.

Binding international legal instruments on action against trafficking in human beings

United Nations Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography

The first binding international legal instrument explicitly covering trafficking in human beings for the purpose of organ removal was the *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography*. The *United Nations Convention on the Rights of the Child*[175] is without any doubt the central international legal instrument for the protection of children. Article 1 of the convention sets the standard for all international legal measures involving children, with the definition of a child being every human being below the age of eighteen years – unless under the law applicable to the child, majority is attained earlier.

In the context of trafficking in human beings, Articles 34 to 36 should also be mentioned: Article 34 covers all forms of sexual exploitation and sexual abuse, Article 35 the abduction of, the sale of or traffic in children for any purpose or in any form and Article 36 all other forms of exploitation prejudicial to any aspects of the child's welfare.

The *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography*[176] elaborates more specifically on those aspects in defining in Article 2 (a) the term "sale of children" as "any act or transaction whereby a child is transferred by any person or group of persons to another for remuneration or any other consideration". In this context, according to Article 3 (1), the following acts and activities must be fully covered under the criminal law of the parties, whether committed domestically or transnationally:

> (i) offering, delivering or accepting, by whatever means, a child for the purpose of:
>
> a. sexual exploitation of the child;

175. General Assembly Resolution 44/25 of 20 November 1989, entered into force on 2 September 1990.

176. General Assembly Resolution A/RES/54/263 of 25 May 2000, entered into force on 18 January 2002.

b. transfer of organs of the child for profit;
c. engagement of the child in forced labour.

In contrast to the convention, where only sexual and labour exploitation are explicitly mentioned and trafficking in human beings for the purpose of organ removal can only be subsumed under "other forms of exploitation" (Article 36), "offering, delivering or accepting, by whatever means, a child for the purpose of transfer of organs of the child for profit" is specifically mentioned in Article 3 (1) (a) (i) (b) of the Optional Protocol.

United Nations Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organised Crime

The Ad Hoc Committee on the Elaboration of a Convention against Transnational Organised Crime set up by United Nations General Assembly Resolution 53/111 of 9 December 1998 to elaborate a comprehensive international convention against organised transnational crime and – among others – an international instrument addressing trafficking in women and children, began its work on 19 January 1999 and held 12 sessions.

The United Nations Convention against Transnational Organised Crime and the Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the *United Nations Convention against Transnational Organised Crime*, were opened for signature at the High-level Political Signing Conference in Palermo (Italy) from 12 to 15 December 2000 and entered into force on 25 December 2003. By December 2008, there were already 117 Signatories and 124 Parties to the Protocol.

The United Nations Trafficking in Persons Protocol itself is a milestone in international measures against trafficking in human beings. For the first time, a comprehensive definition of trafficking in human beings, in which exploitation was not limited to various kinds of sexual and labour exploitation but also included exploitation for the removal of organs, was agreed upon at universal level. Moreover, the protocol deals not only with criminal aspects but also has a broader scope, involving prevention and protection measures, as well as provisions on co-operation.

Council of Europe Convention on Action against Trafficking in Human Beings

On 30 April 2003, the Council of Europe's Committee of Ministers approved the proposal to prepare a Council of Europe Anti-Trafficking Convention and adopted *the specific terms of reference setting up the multi-disciplinary Ad Hoc Committee on Action against Trafficking in Human Beings (CAHTEH)*, whose task was the preparation of a convention focusing on the protection of the human rights of the victims of trafficking and, balanced with this concern, the prosecution of traffickers.

The CAHTEH started negotiations in September 2003 and held eight meetings to finalise the text. The Council of Europe Anti-Trafficking Convention is the most comprehensive international legal instrument on combating trafficking in human beings. It covers all forms of trafficking (national, transnational, whether linked to organised crime or not) based upon the definition in the United Nations Trafficking in Persons Protocol, in particular with a view to victim protection measures and international co-operation. Among other matters, the convention deals with prevention and co-operation, measures to protect and promote the rights of victims, criminal law and co-operation. Its main added value is the monitoring mechanism to ensure that parties implement its provisions effectively.

The Council of Europe Anti-Trafficking Convention was adopted by the Committee of Ministers on 3 May 2005 and opened for signature in Warsaw on 16 May 2005, on the occasion of the 3rd Summit of Heads of State and Government of the Council of Europe. It entered into force on 1 February 2008. By December 2008 it had been signed by 40 states and ratified by 20.

The application of international standards to organ removal

Definitions

The United Nations Trafficking in Persons Protocol for the first time sets out a comprehensive definition of trafficking in human beings in a binding international legal instrument that has been globally accepted. The definition set out in Article 3 of the Protocol was groundbreaking and was therefore adopted in Article 4 of the Council of Europe Anti-Trafficking Convention.

Definition of trafficking in human beings

According to Article 3 (a) of the United Nations Trafficking in Persons Protocol (and Article 4 (a) of the Council of Europe Anti-Trafficking Convention) "trafficking in persons" means "the recruitment, transportation, transfer, harbouring or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose

of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs."

To constitute the crime of trafficking in human beings, a **combination of three basic elements** is necessary:

> an **action** (recruitment, transportation, transfer, harbouring or receipt of persons) by certain **means** (threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person) for the **purpose of exploitation** (which includes at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs).

The actions mentioned (e.g. transport) precede the exploitation, which means that the offence is already constituted if a victim was subjected to one of the actions, by one of the means for one of the purposes.

With regard to trafficking in human beings for the purpose of organ removal, the definition needs to be looked at in more detail to analyse its scope:

Actions: The actions mentioned encompass a variety of activities starting before the actual exploitation and involve more than just the physical transportation from one place to another. As such, they are neutral actions, which become criminally relevant if they are conducted with the intention of exploiting others.

Recruitment is to be understood in a broad sense, meaning any activity leading from the commitment or engagement of another individual to his or her exploitation. It is not confined to the use of certain means and therefore also includes the use of modern information technologies. As the term is described generally, recruitment by one of the means for the purpose of organ removal is regarded as trafficking in human beings for the purpose of organ removal regardless of how the recruitment is performed – whether through personal contact or contact through third persons, newspapers, advertisements or the Internet.

Transportation is also a general term and does not define any particular means or kinds of transportation. The act of transporting a person from one place to another constitutes this element; as in the cases of trafficking in human beings for sexual or labour exploitation, it is not necessary for the victim to have crossed any borders, nor is it necessary for the victim to be present illegally in a state's territory. The offence therefore includes transnational and national trafficking.

The *transfer* of a person includes any kind of handing over or transmission of a person to another person. This is particularly important in certain cultural environments where control over individuals (mostly family members) may be handed over to other people. As the term and the scope of the offence are broad, the explicit or implied offering of a person for transfer is sufficient; the offer does not have to be accepted for the offence of trafficking in human beings to be constituted if the other elements are also present.

The *harbouring* of persons means accommodating or housing persons in whatever way, whether during their journey to their final destination or at the place of the exploitation. This, of course, also includes the accommodation of persons in a medical clinic or other place where the illegal removal of organs is conducted – and the criminal liability of the individuals involved who use one of the means described below to exploit the victims.

The *receipt* of persons is not limited to receiving them at the place where the exploitation takes place either, but also means meeting victims at agreed places on their journey to give them further information on where to go or what to do.

Means: As in all other cases of trafficking in human beings, the means used by the traffickers in cases involving the removal of organs also vary. The words *"threat or use of force"* do not need to be explained explicitly. They indicate in any case that the removal took place against the individual's will, as fear or harm meant the choice was not free and any consent was not established voluntarily.

Other forms of coercion encompass the fact that not only physical harm to the victim but also psychological pressure can limit a person's free will. This may include threatening the victim's family, as well as other forms of economic pressure, etc.

Abduction is a means that is also heard of in connection with cases of trafficking in organs where people are kidnapped and their organs removed. It is in any case a special form of use of force.

Fraud frequently occurs in cases where individuals may initially be willing to have their organs removed and enter into contracts in which they are promised certain sums of money for them. The offence may therefore be constituted in several ways, most commonly by not handing over any money at all to the donors or by paying only part of the agreed sums.

Deception is closely connected with fraud, but should be seen more in terms of cheating as regards a person's knowledge and will than as regards economic aspects. Deception includes misleading individuals about facts, conveying falsehoods or withholding the truth or relevant information from donors, thereby compounding their misconceptions or ignorance. In the case of exploitation for organ removal, the issue of informed consent is of major importance in this respect. Only

if a person is fully informed about the operation itself, its risks and long-term consequences, can informed consent to the medical intervention be given. The offence can therefore be established if the donor is not fully informed about the risks of the removal or the need for follow-up care, is promised medical follow-up which is subsequently not provided and also, e.g., if he or she is misled about the need for the medical indication for the removal of an organ.

The *abuse of power* is especially relevant in cases where an individual has the power to take decisions over other people, e.g. medical doctors who infringe laws and ethical requirements and remove organs from individuals in order to sell the organs even though there was no medical indication for the removal of the organs and no will to donate.

According to the *travaux préparatoires* of the United Nations Trafficking in Persons Protocol,[177] the misuse of a *position of vulnerability* refers to any situation in which the person involved has no real and acceptable alternative but to submit to the abuse involved. The vulnerability can be of any kind: physical, psychological, economic, social, emotional, legal (e.g. illegal residence in a country), etc. In general, the person in question must be in such a situation that he or she virtually has no choice and has to accept being exploited.

The *giving or receiving of payments or benefits to achieve the consent of a person having control over another person* in particular refers to the misuse of a person's authority over another individual, especially with regard to children and persons who are not capable of giving full and valid consent. According to international standards (see, for instance, Article 6 of the *Council of Europe Convention on Human Rights and Biomedicine*), an intervention may only be carried out on such a person for his or her direct benefit and with the authorisation of his or her representative. The element can therefore be constituted if the representative misuses his or her power in agreeing to the intervention contrary to the victim's benefit, human rights and human integrity. The above-mentioned cultural environments where there are situations of "ownership" over other persons also fall under this term.

In general, it should be noted that many of these means are closely interrelated and, in some cases, may be seen more as various degrees than as different means. However, for the offence of trafficking in human beings, the particular means used is of no relevance; if any of the means was used in one of the actions described with the purpose of exploitation in one of the forms indicated, then the crime is deemed to have been committed.

Purpose: This provision stipulates that the perpetrator's intention was the exploitation of an individual. As with the removal of organs, given the severity of possible injuries, risks and (long-term) consequences for the donor, it means that the removal of an organ from a living donor for another person's benefit cannot be justified. If the removal is nonetheless carried out, it in any case results in a severe bodily injury with long-lasting and sustainable consequences which is punishable in any country, even if no special provisions on trafficking in human beings for the purpose of organ removal or on trafficking in organs exist.

It is not necessary for the organ to be removed at the phase where the perpetrator was involved in the process, nor is it necessary for the organ to be removed at all. What matters is that one of the actions was committed with one of the means with the purpose of exploitation of an individual for organ removal. Even persons recruiting potential donors using one of the illicit means and intermediaries and brokers can therefore be held liable under this provision.

The principle that the human body or parts of it must not give rise to financial gain is an accepted international standard and established Council of Europe legal *acquis* (see, in particular, Article 21 of the *Convention on Human Rights and Biomedicine* and Article 22 of the *Additional Protocol concerning transplantation of organs and tissues of human origin*).

As already mentioned, the definition specifically includes only removal of organs, while at the same time stating that this is just a minimum. National legislation can therefore go further and include the purpose of removal of cells and tissues. This is not only consistent with the text of the definition, it is also in line with the spirit of the documents, especially as the means and actions employed are the same as for the removal of organs and the potential health consequences for the victims may be the same. For example, in the case of reproductive cells, exploitation takes place if they are removed in such quantities (once or on several occasions) that severe health problems may result for the donor. If the removal of organs or cells take place for medical reasons (to re-establish or improve the health of the individual, in case of a tumour, etc.), no exploitation occurs. It therefore seems advisable to include the purpose of removal of cells and tissues in national legislation.

Definition of victim

The United Nations Trafficking in Persons Protocol does not define the meaning of victim of trafficking in human beings. Article 4 (e) of the Council of Europe Anti-Trafficking Convention defines victim as "any natural person who is subject to trafficking in human beings as defined in this article", i.e. as defined in Article 4 (a) (see above). It is therefore the only binding international document which gives a definition of victim of trafficking in human beings. A victim

177. Travaux préparatoires: United Nations Convention against Transnational Organised Crime; A/55/383/Add.1, paras. 63-68; interpretative notes on Article 3.

of trafficking in human beings for the purpose of organ removal is accordingly defined as any person recruited, transported, transferred, harboured or received, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation by way of removal of organs.

The issue of consent

Article 3 (b) of the United Nations Trafficking in Persons Protocol refers to the issue of the consent of a victim of trafficking in persons to the intended exploitation set forth in Article 3 (a) and provides that such consent is irrelevant where any of the means set forth in Article 3 (a) have been used.

This basically means that consent to the exploitation is legally impossible if such consent has been obtained by the illicit means mentioned in Article 3 (a). The question of consent is a tricky one, as it may sometimes be difficult to determine where free will and self-determination end and undue pressure begins. Some people may even know what they are consenting to, but they may not be completely aware of all the risks and especially the (long-term) consequences they will be facing – and they would not consent if they did know. It is important that this provision establishes the offence regardless of whether the victim consented to his or her exploitation, as otherwise the defence might raise the argument that the victim had consented to the exploitation and that therefore the offence was not constituted and the perpetrator was not liable.

Article 3 (b) makes it clear that in any case in which one of the activities occurred and one of the means mentioned in the definition of trafficking in human beings (Article 3 (a)) was used for the purpose of exploitation, the offence is constituted, even if consent might appear to have been given – such consent is deemed to have been invalidated by the perpetrator's use of illicit means. In other cases where there never was apparent consent, the offence is deemed to have been committed without this extra step of investigating whether such means were used.

It is also important that the (valid) consent of the victim at one stage of the process may not be taken to be consent for the entire process – consent may be withdrawn voluntarily at any time.

In contrast to trafficking in human beings for sexual or labour exploitation, where there is merely a general notion as to the requirements for consent, in the case of trafficking in human beings for the purpose of organ removal, there are internationally recognised standards for consent which can be inferred from legal documents dealing with organ and cell transplantations.

Alongside the *WHA Guiding Principles on Human Organ Transplantation*, Article 19 of the *Council of Europe Convention on Human Rights and Biomedicine* provides that, in the case of organ removal, the necessary consent must have been given expressly and specifically either in written form or before an official body, e.g. a court or a notary. Article 20 (1) prohibits organ or tissue removal from a person who does not have the capacity to consent.

The issue of consent with respect to the removal of organs is dealt with more comprehensively in the *Additional Protocol to the above Convention concerning Transplantation of Organs and Tissues of Human Origin*. Under Article 12 of the Additional Protocol, the donor and/or person or body responsible for approving such an intervention if the donor is unable to consent must be given appropriate information beforehand regarding the purpose and nature of the removal and its consequences and risks, as well as the legal rights and safeguards. The information must be comprehensive, in a language and form the potential donor understands and he or she must be given sufficient time to decide. Under Article 13 of the *Additional Protocol*, the donor must give free, informed and specific consent to the removal either in written form or before an official body, which he or she can withdraw at any time.

Article 14 of the *Additional Protocol* on the protection of persons not able to consent to organ or tissue removal repeats Article 20 of the *Council of Europe Convention on Human Rights and Biomedicine*.

For further details, please refer to **Existing international standards**, page 34. In any case, the requirements set out in these instruments must be regarded as those which must be met to establish valid consent.

There is only one exception to the general rule that a combination of the three elements, action, means and purpose, is needed for the crime of trafficking in human beings to be committed: in the case of **child victims**, trafficking does not require any of the above-mentioned means to be involved. It is also immaterial whether or not the child has consented to the exploitation. Article 3 (d) of the United Nations protocol expressly provides that child means persons under the age of 18.

To avoid misunderstandings, the drafters of the United Nations Trafficking in Persons Protocol noted that the removal of organs from children with the consent of a parent or guardian for legitimate medical or therapeutic reasons should not be considered exploitation.[178] However, this also sets the limit for legitimate consent of parents or guardians; if they consent to removal of organs other than for legitimate medical or therapeutic reasons, the offence of trafficking in human beings is committed. Regard-

178. Interpretative notes on Article 3 regarding subparagraph (a) in lit. (c) of the protocol approved by the Ad Hoc Committee and included in its report on the work of its first to eleventh sessions (see A/55/383/Add.1, paras. 63-68).

ing the question of what legitimate medical or therapeutic reasons are, reference must again be made to recognised medical and ethical standards.

The provisions in Article 3 (b) of the United Nations Trafficking in Persons Protocol were included in Article 4 (b) of the Council of Europe Anti-Trafficking Convention.

Criminalisation

Article 5 of the United Nations Trafficking in Persons Protocol requires states to adopt such legislative and other measures as may be necessary to establish as criminal offences the conduct set forth in Article 3 of the protocol, when committed intentionally (Article 5 (1)), as well as attempting to commit, participating in and organising or directing other persons in the commission of offences established in accordance with paragraph 1 of the article (Article 5 (2)).

The protocol does not require states to criminalise the individual elements and addresses them solely in the context of trafficking in human beings. It requires states to establish the combination of the elements as a criminal offence. Moreover, according to Article 3 (b), the consent of the victim does not alter the trafficker's criminal liability. The exploitation does not actually have to have taken place. The text leaves it to states to decide how to implement the provisions: first of all, states may decide whether to implement Article 3 by way of the adoption of one or of several provisions. It is also left to states to decide whether Article 5 (2) is implemented by way of general provisions in their national legal systems regarding attempts to commit the offences and aiding and abetting others to do so, or by the introduction of special provisions. The article merely establishes the principle that all the said activities and types of conduct must be criminalised.

The Council of Europe Anti-Trafficking Convention lays down the same requirements, namely in Article 18 ("Criminalisation of Trafficking in Human Beings") and in Article 21 ("Attempt and Aiding or Abetting").

Regarding children, Article 3 (1) (i) (b) of the *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography* provides for the criminalisation of the offering, delivering or accepting, by whatever means, a child for the purpose of transfer of organs of the child for profit, whether committed domestically or transnationally. It is left to states to make this a specific criminal provision or to include it in a general provision criminalising trafficking in human beings (for organ removal). The requirement itself must also be interpreted with respect to the interpretative notes on the United Nations Trafficking in Persons Protocol, according to which the removal of organs from children with the consent of a parent or guardian for legitimate medical or therapeutic reasons should not be considered exploitation. It is a provision designed to protect children as one of the most vulnerable groups. In addition to the special requirements for consent regarding children and persons not legally able to consent, this provision establishes further protective measures to prevent advantage being taken of children. Parents or legal guardians may therefore consent to the transfer of organs of their child for legitimate medical or therapeutic reasons only: in no case, however, may they offer, deliver or accept a child or his or her organs for profit. National legislation must establish criminal provisions to punish such behaviour.

Criminalisation of the use of the services of the victim

According to Article 19 of the Council of Europe Anti-Trafficking Convention, states must consider adopting a provision that criminalises persons who **knowingly** use the services of a victim of trafficking in human beings. None of the other international legal instruments regarding trafficking in human beings includes a provision of this kind. It does not in any sense seek to restrict victims' economic well-being or hinder their social rehabilitation, but is intended to punish those who exploit their services and thereby take advantage of and/or profit from the person's exploitation in the knowledge that he or she is a victim of trafficking in human beings. On the other hand: if somebody is unaware that the person is a victim of trafficking in human beings, he or she cannot be punished. Consequently, the provision has not been made binding, but is still considered to form part of the added value of the convention.

The case of the removal of organs differs significantly from the other forms of exploitation. While several services from victims of sexual or labour exploitation come to mind, it is rather difficult to think of services of victims of organ exploitation. Indeed, the explanatory report on the convention does not give any examples either. The service which such a victim would give would most certainly be the donation of the organ – and, consequently, the use of the service would be the removal of the organ for the purpose of implantation into another person. And here there is a major difference compared to the other forms of exploitation, in particular for the person receiving the service. If a person knowingly uses a victim's sexual or labour services, it might be difficult to prove the knowledge of the fact in practice, but there is no doubt that the relevant conduct cannot be justified, as the person has the choice not to make use of the service without encountering negative consequences. In the case of organs, the situation is trickier.

As already mentioned several times, it is an undisputed principle that the human body and parts thereof must not give rise to any financial profit. *The Council of Europe Convention on Human Rights and Biomedicine*, the *Additional Protocol* to the Convention

concerning Transplantation of Organs and Tissues of Human Origin and the *WHA Guiding Principles on Human Organ Transplantation* all reiterate this principle, which is the basic provision for preventing and combating illegal trade and trafficking in organs. It is an important rule for protecting human rights and the altruistic nature of organ donations. Nobody should profit financially from the sale of body parts – and clear political will is shown that no brokers, medical staff, health institutions or others should profit financially from a commercial transaction between third persons, namely the donor(s) and the recipient(s) of organs, almost all of whom are in a desperate and vulnerable situation.

Similar to donors who often find themselves in situations where they see no alternative but to participate in the transaction, the situation of recipients is almost always desperate. (Potential) recipients of organs from victims of trafficking in human beings are in such a desperate situation because they most probably have tried everything to obtain an organ legally, but without success. And they also face severe consequences if they fail to obtain an organ, ranging from further dependence on life-prolonging measures which do not have the same therapeutic effect as organ transplantations through to death. The recipients are therefore under enormous pressure which must also be taken into account.

These cases cannot therefore be treated on the same basis as the others, i.e. either users of services of victims of sexual and labour exploitation or brokers and health staff who participate in transplantations for their financial benefit only. Criminal liability therefore has to be discussed very sensitively. If a potential recipient abets somebody to initiate the illegal removal of an organ from another person, he or she is directly liable for trafficking in human beings for the purpose of organ removal in connection with abetting (Articles 3 and 5 (2), United Nations Trafficking in Persons Protocol, and Articles 18 and 21, Council of Europe Anti-Trafficking Convention).

On the other hand, travelling to another country and thereby circumventing stricter laws in one's own country (transplant tourism) in the knowledge that the organs may most probably come from a person in a desperate situation who might be a victim is definitely morally and ethically highly reprehensible behaviour which should be prevented as far as possible. However, it also reflects the hopeless situation of the individual, which should be taken into account when discussing whether such behaviour should be criminalised or whether other sanctions and measures (especially measures to increase the availability of organs, in particular from deceased persons) should be developed to prevent the need for and hence the commission of such acts.

In this context, it is worth noting that situations may arise where recipients can be excluded from criminal liability because of their emergency situations or other exculpating factors. The complexity of the issue was one of the reasons that no agreement could be reached on the draft EU *framework decision concerning the prevention and control of trafficking in human organs and tissues,* as several states had objections to a provision of this kind.

Criminalisation of living donors

Another sensitive issue is the criminalisation of living donors. First of all, it should be stated clearly that a living donor can be a potential victim of trafficking in human beings for the purpose of organ removal, but not a potential perpetrator in a case related to his or her person; this is impossible under the definition, as no activities can be conducted with the relevant means to exploit oneself. However, it is, of course, possible for a living donor to be involved in the exploitation of another person and become a perpetrator with regard to that person. And, of course, criminal liability is possible if the living donor infringes national laws which forbid such behaviour, in particular the selling of organs for profit to third persons. It must be made clear, however, that this involves criminal liability for trafficking in organs, not trafficking in human beings for the purpose of organ removal.

The criminalisation of such donors is sensitive, as in many cases they have been deceived or coerced by criminal groups or their desperate economic situation has forced them to participate in the transaction. As they are likely to suffer from the consequences of the removal and to become victims of trafficking in human beings at the latest once their organ has been removed, states should refrain from holding these individuals criminally liable. In this respect, reference should be made to Article 26 of the Council of Europe Anti-Trafficking Convention, the so-called "non-punishment provision", according to which states must, in accordance with the basic principles of their legal system, provide for the possibility of not imposing penalties on victims for their involvement in unlawful activities, to the extent that they have been compelled to take part in such activities. Article 26 leaves it to states to comply with this provision by establishing either a substantive criminal provision or a procedural criminal-law provision – or any other measure, which also (alternatively) means administrative law provisions because Article 26 does not restrict the requirement to establishing criminal provisions. Article 26 must also be applied to unlawful activities which are covered not by criminal law but by administrative law (e.g. illegal entry into or residence in a country's territory, etc.).

In its *draft legislative resolution on the Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs*

and tissues,[179] the European Parliament also called, inter alia, for the provision which would make living donors criminally responsible for selling or offering to sell their organs to be deleted because the main aim of the initiative should be to tackle the agents of the illegal trafficking in human organs, not to exacerbate the suffering of its victims.[180] States should therefore refrain from holding living donors liable for any participation in activities connected to trafficking in human beings for the purpose of organ removal, except for cases when they start actively participating in trafficking activities involving other persons and become traffickers themselves.

Criminalisation of medical staff, brokers, intermediaries, etc.

Considering the broad definition and the accompanying provisions on aiding or abetting, many of the persons involved in the whole process of trafficking in human beings can be held liable under these provisions. In addition to the explanations above, the following principles apply:

Brokers who try to find potential donors should be considered as falling directly within the scope of Article 5 of the United Nations Trafficking in Persons Protocol (Article 18 of the Council of Europe Anti-Trafficking Convention) if they use one of the illicit means, which mostly is the case, as the action must then be considered most often as recruitment. Other intermediaries should also be considered as falling directly within the scope if they use deceit, threats or one of the other means in transferring, transporting, harbouring or receiving the victim prior to exploitation. In addition, there are always possible situations in which they can be held liable for aiding or abetting the perpetrators.

The position is somewhat different for medical staff. If they are directly involved in the trafficking process with one of the activities mentioned, they commit the crime as direct perpetrators. They may also be held liable for aiding and abetting if they do not actually perform any of the actions themselves, but aid or abet the traffickers, e.g. by deceiving the victim about the risks or dangers of the removal of organs or the need for and amount of follow-up care, etc., in order to obtain the victim's consent.

Doctors "just" giving information about the possibility of transplant tourism without any further involvement are not guilty of trafficking in human beings, as their action would be too limited to be regarded as falling under the term "recruitment". Guiding Principle 7 of the *Revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation* bears in mind that physicians may find themselves in situations where they meet patients willing to pay for cells, tissues or organs and underlines that they should not refer them to transplant facilities – in their own or other countries – that make use of cells, tissues or organs obtained commercially, or seek or accept payment for doing so. Nonetheless, such behaviour may infringe other legal and ethical provisions and may lead to criminal liability because of other offences.

The same applies to doctors involved in the follow-up care of individuals who obtained illegal transplants. If such doctors were not directly involved in the exploitation of the victim, but confronted with the recipient after the transplantation, they cannot be held liable for trafficking in human beings. Moreover, in accordance with the medical and legal standards applicable in many countries, doctors will not be in a position to deny the recipient medical care and may be bound by rules on medical secrecy (see also the commentary on Guiding Principle 7 of the *Revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, which explicitly takes note of such situations and states that doctors should not face professional sanctions if they decline to provide post-transplant care for patients who have undergone transplantation at facilities of the above kind, provided that they refer such patients elsewhere). However, if national legislation requires them to inform the authorities about such cases and they breach these requirements, they may be held liable for infringements of those provisions.

In the case of hospitals and hospital staff, the provisions regarding criminal liability of legal persons also have to be taken into account. If hospitals or natural persons with a leading position in them are involved in trafficking activities for the benefit of the hospitals, then criminal liability can be established for both the natural and the legal persons. If the hospital (staff) know(s) about the planned or ongoing trafficking activities or is/are actually facilitating or actively offering potential donors, then the action (in any case harbouring, as the victims are accommodated in the hospital; but possibly also recruitment or receipt) and the purpose (exploitation) are established, and the third element, the use of illicit means, will most often also occur if the victims are deceived (about the need for the intervention, the risks, the consequences, the price, etc.), threatened or if advantage is taken of their vulnerability, etc.

Criminalisation of acts relating to travel or identity documents

Article 20 of the Council of Europe Anti-Trafficking Convention requires the following to be established as criminal offences, when they are committed intentionally and for the purpose of enabling trafficking in human beings: forging a travel or identity document (a), procuring or providing such a document (b) and retaining, removing, concealing, damaging or destroying a travel or identity document of another person (c).

179. 7247/2003 – C5-0166/2003 – 2003/0812 (CNS).
180. Draft European Parliament legislative resolution; Justification regarding amendment 31.

This is an important provision for preventing international trafficking in human beings for the purpose of organ removal, as many (potential) donors cross national borders to sell their organs in a country other than their country of origin because traffickers often use false documents to traffic victims in other states and exert pressure on them by withholding their documents and thus increasing their dependence.

For this to be fully effective, states must have effective border control measures (Article 11, United Nations Trafficking in Persons Protocol, and Article 7, Council of Europe Anti-Trafficking Convention) and systems to ensure the integrity and security of travel or identity documents (Article 12, United Nations Trafficking in Persons Protocol, and Article 8, Council of Europe Anti-Trafficking Convention) and must verify within a reasonable time the legitimacy and validity of travel or identity documents (Article 13, United Nations Trafficking in Persons Protocol, and Article 9, Council of Europe Anti-Trafficking Convention) issued or purported to have been issued in their name.

Sanctions

Article 5 of the United Nations Trafficking in Persons Protocol requires states to adopt such legislative and other measures as may be necessary to establish as criminal offences the conduct of intentional trafficking in human beings (Article 5 (1)) and attempting to commit, participating in and organising or directing other persons in the commission of such offences (Article 5 (2)).

Article 23 (1) of the Council of Europe Anti-Trafficking Convention requires states to adopt measures to ensure that the criminal offences established in the convention are punishable by **effective, proportionate and dissuasive sanctions**, including, in the case of the crime of trafficking in human beings, penalties involving deprivation of liberty which can give rise to extradition.

For the crime of trafficking in human beings, Article 24 of the Council of Europe Anti-Trafficking Convention requires states to regard the following circumstances as aggravating circumstances when determining the penalty:

- the offence deliberately or by gross negligence endangered the life of the victim (a),
- the offence was committed against a child (b),
- the offence was committed by a public official in the performance of her/his duties (c), and
- the offence was committed within the framework of a criminal organisation (d).

In addition, under Article 25 of the Council of Europe Anti-Trafficking Convention, states must provide for the possibility of taking into account final sentences passed by other states in relation to offences mentioned in the convention when determining the penalty. This does not involve an obligation for national judges or public prosecutors actively to investigate whether such previous convictions exist, but means that – if such are known – they must be taken into account when penalties are determined. They will then have to be regarded as aggravating circumstances and will most probably lead to higher sentences in the event of convictions.

Other criminal law provisions

Article 1 (3) of the United Nations Trafficking in Persons Protocol expressly states that the offences established in accordance with Article 5 of the protocol are to be regarded as offences established in accordance with the *UN Convention on Transnational Organised Crime* (UNTOC). According to Article 1 (2), the provisions of the *UNTOC* apply, *mutatis mutandis*, to the protocol unless otherwise provided. All the provisions in the *UNTOC* regarding criminal procedural measures and international legal co-operation therefore also apply to the crime of trafficking in human beings under the United Nations Trafficking in Persons Protocol. This includes such important accompanying measures as those to combat money laundering and corruption, two crimes which are closely linked to organised trafficking in human beings.

Criminalisation of legal persons

According to Article 10, *UNTOC*, (and Article 22, Council of Europe Anti-Trafficking Convention), legal persons must be held criminally liable for their participation in trafficking in human beings for the purpose of organ removal involving an organised criminal group and must be subject to effective, proportionate and dissuasive sanctions, which, according to Article 23 (2) of the Council of Europe Anti-Trafficking Convention, includes monetary sanctions. This is an important principle because, in implementing these measures, not only the traffickers themselves but also institutions like hospitals involved in the trafficking network are criminalised and are subject to penalties.

Confiscation and seizure

States are required to implement provisions on confiscation and seizure (Articles 12 to 14, *UNTOC,* and Article 23 (3), Council of Europe Anti-Trafficking Convention) of proceeds of crime or of property corresponding in value to that of such proceeds derived from trafficking in human beings and of property, equipment or other instrumentalities used in or destined for use in trafficking in human beings. These measures are effective tools because the main motivation for this crime is financial profit and it is therefore necessary to confiscate the money from the traffickers. The *UNTOC* also contains provisions on extradition, mutual legal assistance, joint investigations and special investigative techniques. They round off the legal framework which needs to be established in order effectively and

comprehensively to combat trafficking in human beings.

Closure of establishments and denial of the exercise of duties

Under Article 23 (4) of the Council of Europe Anti-Trafficking Convention, states must also adopt measures to enable the temporary or permanent closure of any establishment which was used to carry out trafficking in human beings, without prejudice to the rights of *bona fide* third parties, or to deny the perpetrator, temporarily or permanently, the exercise of the activity in the course of which the offence was committed. In the event of health facilities and hospitals being involved in the trafficking activities, this would require their closure to prevent further cases. In addition, doctors, nurses and other staff intentionally participating in any activities related to trafficking in human beings for the purpose of organ removal (information, examinations, transplantations, providing care, recruiting, accommodating, etc.) would have to be denied the right to exercise their duties, which would be an effective tool for combating trafficking in human beings for organ removal and trafficking in organs.

Ex-officio applications

Under Article 27 of the Council of Europe Anti-Trafficking Convention, states must ensure that investigations into and prosecution of trafficking offences do not depend on the report or accusation made by a victim. If individuals fall victim to trafficking in another state, the competent authorities either have to take action themselves or transmit the complaint without delay to the competent authority of the country in which the offence was committed.

Victim assistance in criminal proceedings

Article 27 (3) of the Council of Europe Anti-Trafficking Conventionis one of the key provisions highlighting the human rights approach of this instrument, which also places emphasis on co-operation with civil society. In accordance with the conditions provided for under internal law, states must ensure that any group, foundation, association or non-governmental organisation which seeks to combat trafficking in human beings or protect human rights is able to assist and/or support the victim, with his or her consent, during criminal proceedings.

Protection during and after criminal proceedings

Under Article 28 of the Council of Europe Anti-Trafficking Convention, victims, witnesses, when necessary, members of their families and individuals who co-operate with judicial authorities must be afforded effective and appropriate protection from potential retaliation or intimidation, in particular during and after investigation and prosecution of perpetrators. Such protection may include physical protection, relocation, identity changes and assistance in obtaining employment. This provision is primarily aimed at protecting the victims, but is also an important tool for law enforcement because, only if victims feel that they and their family members are sufficiently safe and secure, will they be willing to co-operate in criminal proceedings against perpetrators and, as experience shows, such co-operation is crucial for convictions in most trafficking cases.

Article 6 (1) of the United Nations Trafficking in Persons Protocol requires states to provide for the possibility of confidential legal proceedings for the sake of the protection of victims. Article 30 of the Council of Europe Anti-Trafficking Convention also takes note of the need to protect victims in court proceedings and to balance this with the need to ensure a fair trial. Measures to ensure the protection of victims' private life and, where appropriate, identity, as well as their safety and protection from intimidation, therefore have to be provided in the course of judicial proceedings. Because of the differences in legal systems, it is left to states to decide how to achieve these aims. According to the case-law of the European Court of Human Rights, the following measures could be used, for instance:

- non-public hearings (for part or all of the trial if required by the interests of a juvenile or the protection of the private life of a victim),
- anonymous testimony (avoidance of the public disclosure of the identity of victims, while at the same time guaranteeing the defence an adequate opportunity to question the victim),
- use of audio and video technology: for taking evidence and conducting hearings to avoid the repetition of hearings and face-to-face contact between the victim and the perpetrator (to avoid any kind of pressure or undue influence that might deter victims from giving evidence), and
- the possibility of using make-up or disguise.

In the event of a conviction, the extent of the handicaps to the defence must be taken into account so as to create a fair balance with the defence rights and provide for a fair trial.

Victim protection

Protection of the privacy and identity of victims of trafficking in human beings

This is essential both to ensure the physical protection of victims and their families from the perpetrators and also to avoid them suffering additional psychological pressure. It is also necessary in order to protect their chances of social reintegration. Legal proceedings (especially, but not only, court proceedings) in cases of trafficking in human beings can aggravate the unfortunate consequences for the victims. In addition, media coverage can seriously invade victims' privacy, resulting in stigmatisation and making it even more difficult for victims to reintegrate socially. Article 6 (1) of the

United Nations Trafficking in Persons Protocol and Article 11 of the Council of Europe Anti-Trafficking Convention therefore require the protection of the privacy and identity of victims. They also require measures to ensure that the identity, or details allowing the identification, of a child victim of trafficking are not made publicly known, except, in exceptional circumstances, in order to facilitate the tracing of family members or otherwise secure the well-being and protection of the child.

Physical, psychological and social recovery of victims

Whereas Article 6 (3) of the United Nations Trafficking in Persons Protocol is non-binding, Article 12 (1) of the Council of Europe Anti-Trafficking Convention requires states to adopt such measures as may be necessary to assist victims in their physical, psychological and social recovery. It should be expressly reiterated and underlined that the adoption of these measures is an obligation for all states – both countries of origin and countries of destination. The vulnerability of victims does not end at borders. On the contrary, victims need this assistance whether they remain in a country or are repatriated or returned to their country of origin – in both situations, these measures are necessary for the victim's social recovery and social reintegration. The following measures are to be regarded as the minimum assistance to be provided ("in particular" (United Nations Trafficking in Persons Protocol), "at least" (Council of Europe Anti-Trafficking Convention)):

Standards of living capable of ensuring their subsistence: Article 12 (1) (a) of the Council of Europe Anti-Trafficking Convention requires states to provide services guaranteeing a certain standard of living to ensure victims' subsistence, in particular:

Appropriate housing (Article 6 (3) (a), United Nations Trafficking in Persons Protocol), appropriate and secure accommodation (Article 12 (1) (a), Council of Europe Anti-Trafficking Convention)

It is not enough for the victim to be accommodated after his or her identification; he or she must be housed appropriately and safely. Shelter can be provided in facilities provided by governmental or non-governmental institutions. However, detention centres or other facilities where victims' freedom of movement is restricted are not considered to be appropriate. If the victim is suffering from health problems resulting from the removal of an organ, the appropriateness of the housing will also depend on whether the quality of the shelter is sufficient to take the health aspects into account; in some cases, only accommodation in a hospital or a comparable health institution may be considered appropriate.

Psychological and material assistance (Article 6 (3) (c), United Nations Trafficking in Persons Protocol), psychological and material assistance (Article 12 (1) (a), Council of Europe Anti-Trafficking Convention)

Victims of trafficking in human beings are often traumatised and need psychological assistance. Material assistance covers adequate and at least basic kinds of support which a victim might need for living, in particular clothes, food, etc.

Medical assistance

Especially in cases of trafficking in human beings for the purpose of organ removal, it is obvious that certain medical assistance is needed as well. The assistance is not supposed to cover all possible kinds of treatment, but at least those which are needed to (re-)establish or ensure the physical safety and integrity of the victim and to record any evidence of the violence for further judicial proceedings. Whereas Article 6 (3) (c) of the United Nations Trafficking in Persons Protocol makes a general reference to medical assistance, the Council of Europe Anti-Trafficking Convention distinguishes between access to emergency medical treatment (Article 12 (1) (b)), which must be granted to all persons whom the authorities have "reasonable grounds to believe" are victims, and more comprehensive "necessary medical or other assistance", which is only to be provided for victims lawfully resident in a state's territory who do not have adequate resources and need such help (Article 12 (3)). "Lawfully resident" means nationals of the state concerned or persons with a residence permit.

However, even with the restriction to emergency medical treatment, denying victims of trafficking in human beings for the purpose of organ removal any follow-up care, as often happens, is incompatible with these provisions. No waiver which a victim may have signed in the belief that the document provides otherwise can relieve states of the obligation to provide for the necessary medical treatment to restore the individual's physical well-being – regardless of how or where the treatment is provided. It may be provided in special healthcare institutions or by certain doctors; how this is done is left up to states; what matters is that the medical care is provided.

Counselling and information, in particular as regards their legal rights, in a language that the victims of trafficking in persons can understand (Article 6 (3) (b), United Nations Trafficking in Persons Protocol, and Article 12 (1) (d), Council of Europe Anti-Trafficking Convention), which includes counselling and information regarding the services available to victims: Victims have the right to be counselled by lawyers and/or support services. The phrase "in particular as regards their legal rights" highlights the importance of those aspects, but also makes it clear that the provision is not restricted to them. It is also important for victims to be

informed about the possibilities regarding all services available to them, especially medical care, employment, repatriation and social integration, etc. It is crucial that the information is given in a language that the victim can understand and that it is given on time, i.e. as soon as possible, so as to enable the victim to exercise his or her rights.
The legal rights may be the rights and duties of victims as witnesses, protection measures available to them, ways to obtain compensation from perpetrators or other persons or entities and possibilities for legalising their residence in a country, etc. The information should enable victims to assess their situation and make an informed decision about the possibilities open to them.

Employment, educational and training opportunities: These measures mentioned in Article 6 (3) (d) of the United Nations Trafficking in Persons Protocol are important for the re-integration of the victim into society; their level and nature depend on the age and knowledge of the victim.
Article 12 (1) (f) of the Council of Europe Anti-Trafficking Convention grants all children for whom there are reasonable grounds to believe that they are victims of trafficking in human beings access to education. Under Article 12 (4), access to the labour market, to vocational training and education only has to be provided for victims of trafficking in human beings lawfully resident within a state's territory.

Information on relevant court and administrative proceedings:
Article 6 (2) (a) of the United Nations Trafficking in Persons Protocol specifically requires information to be provided on relevant court and administrative proceedings. Article 15 (1) of the Council of Europe Anti-Trafficking Convention further stipulates that this information must be given to victims of trafficking in human beings, as from their first contact with the competent authorities, in a language which they can understand. The information must be comprehensive. Regarding court proceedings, it must include details about the scope, length and consequences of criminal proceedings against the perpetrator(s) or even against victims themselves (if criminal proceedings are also launched against living donors in certain countries), as well as about civil proceedings (see Article 6 (3) (b), United Nations Trafficking in Persons Protocol). Information about administrative proceedings relates in particular to possible difficulties which victims could encounter with regard to their residence in the country (if they had travelled to another country for their organ to be removed) or to proceedings involving health insurance issues.

Assistance to enable the views and concerns of victims to be presented and considered at appropriate stages in criminal proceedings against offenders: Under Article 6 (2) (b) of the United Nations Trafficking in Persons Protocol, such assistance must be provided in a manner that is not prejudicial to the rights of the defence. Article 12 (1) (e) of the Council of Europe Anti-Trafficking Convention more specifically refers to assistance to enable the rights and interests of victims to be presented and considered at appropriate stages of criminal proceedings against offenders, thereby drawing more attention to the aim to make sure that the victim's rights are taken into account properly during criminal proceedings. The provisions do not specify whether such assistance should be given by lawyers or special support services, but regardless of how the service is provided, it must enable the victim's perspective to be considered in criminal proceedings. In any case, it is important that states maintain a balance between the rights of the victims and those of the defence so as to guarantee a fair trial.

Translation and interpretation services: Article 12 (1) (c) of the Council of Europe Anti-Trafficking Convention also provides that translation and interpretation services must be provided, when appropriate, as this is a prerequisite for victims being able to exercise their rights and obtain knowledge of and gain access to the services available to them. It is an important provision for ensuring that victims have access to their rights, which is a precondition for access to justice.

Physical safety of victims: Under Article 6 (5) of the United Nations Trafficking in Persons Protocol and Article 12 (2) of the Council of Europe Anti-Trafficking Convention, states must provide for the physical safety of victims of trafficking in persons while they are within their territory. For the sake of completeness, the Council of Europe Anti-Trafficking Convention adds victims' protection needs to this requirement. Account must be taken of the fact that the real needs of the victims may differ from one person to another.

Possibility of obtaining compensation: Article 6 (6) of the United Nations Trafficking in Persons Protocol grants victims the possibility of obtaining compensation for damage suffered, and leaves it to national legal systems to determine the measures by which this requirement is met.
Article 15 of the Council of Europe Anti-Trafficking Convention deals in greater detail with this right and seeks to ensure that victims obtain adequate compensation. Article 15 (3) lays down the right of victims to compensation from the perpetrators. The compensation is financial and covers both material costs (e.g. for medical treatment) and non-material damage. States must establish a legal framework in which victims can claim compensation. This may be in the course of criminal proceedings against traffickers in which the courts decide upon compensation, or in proceedings in civil courts. Full compensation

is rarely obtained because the perpetrators are often not found, disappear or have hidden all their assets. Article 15 (4) therefore requires states to take steps to guarantee compensation for victims of trafficking in human beings. It is left to them to decide how to do this, for instance by setting up a compensation fund or introducing measures or programmes aimed at social assistance and social integration of victims, which could be funded by assets of criminal origin.

Legal aid and legal assistance:

Under Article 15 (2) of the Council of Europe Anti-Trafficking Convention, each state must provide, in its internal law, for the right to legal assistance and to free legal aid for victims under the conditions provided by its internal law. As all kinds of court and administrative procedures are usually very complex and, in particular, difficult to understand for traumatised victims, such assistance is necessary to enable victims to claim their rights. This provision does not grant victims an absolute right to free legal aid, and it is up to individual states to determine the conditions and requirements according to which such aid may be granted to applicants who lack financial means and are therefore unable to afford a lawyer.

All the above measures have in common that they are not restricted to specific categories of countries, i.e. both countries of origin and countries of destination must provide them for victims in an appropriate way. There are no indications that this provision could be understood in the sense of victims being placed in a better position than they would have been in had they not become victims of trafficking in human beings. However, the victims' integrity must be restored and they must be protected, with the above measures being provided on an appropriate level. In any case, in providing these services, states must take into account the age, gender and special needs of victims of trafficking in persons, in particular the special needs of children (Article 6 (4)), United Nations Trafficking in Persons Protocol, and Article 12 (7), Council of Europe Anti-Trafficking Convention).

Moreover, Article 12 reiterates the self-explanatory principle that assistance to victims must not be made conditional on their willingness to act as witnesses (paragraph 6) and that services are provided on a consensual and informed basis (paragraph 7), in other words, assistance is granted on the basis of free and informed consent.

Identification of victims: Article 10 of the Council of Europe Anti-Trafficking Convention tackles the issue that in order for all the measures to be applied to victims, the latter first have to be identified as such. It therefore requires states to provide their competent authorities with trained and qualified persons and ensure co-operation between different authorities and relevant support organisations, so that victims can be identified in a procedure duly taking into account the special situation of women and child victims. If the competent authorities have reasonable grounds to believe that a person has been the victim of trafficking in human beings, states must ensure that the person concerned is not removed from their territory until the identification process has been completed by the competent authorities and also that the person receives assistance. Moreover, in appropriate cases, such persons must be issued with residence permits.

If the age of victims is uncertain and there are reasons to believe that they are children, they must be presumed to be such and must be afforded special protection measures. If an unaccompanied child is identified as a victim, he or she must be provided with legal representation acting in his or her best interests. The necessary steps must also be taken to establish his/her identity and nationality and every effort made to locate his/her family when this is in the child's best interests (i.e. not in cases where the family appears to have sold the child).

The status of victims of trafficking in persons in countries of destination:

When identified, victims who are illegally present in a state's territory or who are legally resident with a short-term residence permit are traumatised after their suffering and are also likely to be removed from the territory. Article 13 of the Council of Europe Anti-Trafficking Convention therefore grants a recovery and reflection period of at least 30 days when there are reasonable grounds to believe that the persons concerned are victims. Such a period must be sufficient for the persons concerned to recover and escape the influence of traffickers and/or to take an informed decision on co-operating with the competent authorities. During this period, no expulsion order may be enforced against them and they must be authorised to remain in the country. However, this provision is without prejudice to the activities carried out by the competent authorities in all phases of the relevant national proceedings, and in particular when investigating and prosecuting the offences concerned. The only case where the provision does not apply is if grounds of public order prevent it or if it is found that victim status is being claimed improperly.

Under Article 7 (1) of the United Nations Trafficking in Persons Protocol, states must permit victims to remain temporarily or permanently in their territory in appropriate cases. Although this is not an absolute right, measures must nonetheless be taken so that victims can remain in a given country in special circumstances. The aspects to be taken into account when considering such cases are humanitarian and compassionate factors (Article 7 (2), United Nations Trafficking in Persons Protocol). Several countries have implemented this provision by way of granting residence permits on humanitarian grounds.

Article 14 of the Council of Europe Anti-Trafficking Convention takes account of the different legal systems within Council of Europe member states and provides that states must issue renewable residence permits to victims if the competent authority considers that their stay is necessary for the purpose of their co-operation with the competent authorities in investigations or criminal proceedings or owing to their personal situation (i.e. on humanitarian grounds) – or in both situations (paragraph 1). The non-renewal or withdrawal of such residence permits is subject to the conditions laid down by national law (paragraph 3). Most importantly, the granting of such residence permits must be without prejudice to the right to seek and enjoy asylum (paragraph 5).

Repatriation and return of victims: The provision on repatriation of victims is an important guarantee for non-discrimination and victims' social reintegration. Victims have the right to return to their countries of origin, which must facilitate and accept their return without undue or unreasonable delay, having due regard for their safety (Article 8 (1), United Nations Trafficking in Persons Protocol, and Article 16 (1), Council of Europe Anti-Trafficking Convention). Paragraph 2 of both instruments sets out the corresponding obligation for countries of destination, which must also have regard for victims' safety when returning them. They must also take into account the status of legal proceedings related to the fact that the persons are victims, in order not to affect the rights they could exercise in proceedings (especially with regard to compensation). The repatriation of victims should preferably be voluntary.

Accompanying provisions for paragraph 1 are the requirements that states must verify whether the persons concerned are nationals or have the right of permanent residence (paragraph 3 in both instruments), facilitate their repatriation and therefore also issue the necessary documents or authorisations to enable the victims to travel to and enter their territory (paragraph 4 in both instruments).

The Council of Europe Anti-Trafficking Convention also requires states to establish repatriation programmes designed to avoid re-victimisation (paragraph 5) and to make available to victims contact information for structures which can assist them in the country to which they are returned or repatriated (paragraph 6). Moreover, child victims must not be returned to a state, if there are indications, following a risk and security assessment, that this would not be in the best interests of the child.

Lastly, both instruments require states to take measures for the effective prevention of trafficking in human beings and re-victimisation, to promote co-operation with civil society, to tackle the root causes (poverty, underdevelopment, lack of equal opportunity) and to discourage demand. Information exchange and staff training are also called for.

IV. Conclusions and recommendations

"Trafficking in organs, tissues and cells" and "Trafficking in human beings for the purpose of the removal of organs": two different phenomena and two different crimes

One of the major aims of this Joint Study has been to distinguish between "Trafficking in OTC" and "Trafficking in human beings for the purpose of removal of organs". The two are frequently mixed up in public debate and in the legal and scientific community. This leads to confusion and consequently hinders effective efforts to combat both phenomena and also to provide comprehensive victim protection and assistance.
Some trafficking in OTC may originate in trafficking in human beings and will therefore fall within the scope of both international legal instruments mentioned above. But trafficking in OTC is much broader in scope than trafficking in human beings for the purpose of organ removal. Indeed, in the broader context of trafficking in OTC, trafficking in human beings for the purpose of organ removal might be considered a marginal phenomenon. On the other hand, trafficking in human beings covers types of exploitation other than the removal of organs and is therefore more than an issue of trafficking in organs: trafficking in human beings involves a combination of three basic elements (action, means and purpose) which may not necessarily be present in cases of trafficking in OTC.
As mentioned above, "Trafficking in OTC" and "Trafficking in human beings for the purpose of removal of organs" are two different phenomena despite the confusion that exists between them. The "trafficked objects" are different: in one case the "organs, tissues and cells" and in the other case the "person him/herself" who is trafficked for the specific purpose of removing his/her organs. To express this idea in legal terms, it could be said that trafficking in organs, tissues and cells differs from trafficking in human beings for organ removal in one of the constituent elements of the crime – the object of the criminal offence. In the former case, the object of the crime is the organs, tissues and cells, while in the latter case it is the trafficked person.

The prohibition of making financial gains with the human body or its parts: the paramount principle

The principle that it is not permissible for the human body or its parts as such to give rise to financial gain is established Council of Europe legal acquis. It was laid down in *Committee of Ministers Resolution (78) 29 on harmonisation of legislation of member states relating to removal, grafting and transplantation of human substances* and was confirmed, in particular, by the final declaration of the 3rd Conference of European Health Ministers (Paris, 1987) before being definitively established in Article 21 of the 1997 *Council of Europe Convention on Human Rights and Biomedicine [CETS No. 164]*: "The human body and its parts shall not, as such, give rise to financial gain". The principle was then reaffirmed in the 2002 *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [CETS No. 186]*.
Article 22 of this Additional Protocol states: "Organ and tissue trafficking shall be prohibited".

At United Nations level, there is no legally binding instrument which sets out the principle of the prohibition of making financial gains from the human body or its parts. However, the World Health Organisation *Guiding Principles on Human Cell, Tissue and Organ Transplantation* clearly lay down this principle. Although not legally binding, they have been incorporated in many professional standards and laws and are not only widely recognised but also basically undisputed in terms of standard-setting. The principle of the prohibition of making financial gains with the human body is also essential in order not to jeopardise the donation system based on altruism, both from living and from deceased donors, which must be the basis of the organ transplantation system. Legislation on the recovery of organs from living and deceased donors for transplantation should be passed in all countries and should conform to this principle.

Organ donation and organ transplantation: promotion of organ donation, organisational and technical measures to increase organ availability and existence of organisational and technical capacity for transplantation of organs

There is an impressive range of existing recommendations, resolutions and international legally binding instruments dealing with transplantation of OTC. It should be noted that international activities in this area started very early and have since been continued on a consistent basis. When all existing international standards and instruments dealing with transplantation of OTC are considered, it can be seen that there are no discrepancies between them; they complement one another in an internationally recognised body of law. From the outset, the general principles have been very clear: the preference for organs and tissues from deceased persons over those from living persons, the prohibition of financial gains and the need to promote donations and establish appropriate professional standards. These principles have remained the same in substance, but have in the course of time been further developed and clarified. They are set out in all documents and instruments of all major international organisations dealing with this topic: the World Health Organisation, the Council of Europe, the European Union and the recently founded Iberoamerican Network-Council of Donation and Transplantation (RCIDT).

Key organisational measures to increase organ availability and improve the safety and quality of donation and transplantation have been described by all these international organisations and have been given effect in recommendations, declarations and specific actions and activities related to training, education and promotion. However, the extent to which such organisational measures are developed varies significantly between countries, often as a result of limitations affecting their practical implementation. Approaches geared towards an ideal structure for an effective system for deceased donation must take into consideration the particular context of individual countries. Legal, economic, socio-demographic and health-care structural factors and, indeed, social and cultural particularities may have a significant impact on the number of potential donors in a given country and the extent to which the above-mentioned measures are applicable. Efforts need to be made in this regard. It is important to identify and explore models that work in different settings and to promote co-operation at an international level so as to ensure that these best practices are shared. The same applies to technical measures and the degree of development of alternatives to DBD as sources of organs for transplantation. In fact, the use of ECD and DCD varies substantially between countries as a consequence of the many related ethical, legal and practical issues, which should be addressed in a universal fashion but, once again, with a locally tailored approach.

The above paragraphs relate to medical and legal standards. However, there are other important issues that have to be taken into account as well. This mainly involves the promotion of organ donations. Actions like the European Organ Donation Day and the International Organ Donation Day should be continued and supplemented by regional awareness-raising activities and improved information campaigns by governmental and non-governmental organisations. Promotion is considered to be of limited usefulness as a means of effectively combating the shortage of organs for transplantation. However, the campaigns might increase public awareness of the need for organs for transplantation. Transparent information is also crucial to ensure public trust in the donation and transplantation systems.

A point to be stressed is the fact that many of the above measures require the involvement of national authorities in the field of donation of OTC if they are to be effective. The issue of donation and transplantation must be placed on the political agenda. Governments have a central role in establishing laws on transplantation and also in carrying out oversight of donation and transplantation practices in accordance with international standards. The development of successful programmes for deceased donation also needs effective support from health-care authorities, which should invest in such programmes. This is something which has been achieved in many countries, but not in many others. Obviously, donation and transplantation competes with other health-care interventions in many current situations. However, transplantation has proven to be cost-effective even in low-resource environments. Lastly, the organisational and technical capacity to perform transplantation must be developed in all countries, which should not preclude international co-operation when needed.

Co-operation must be strengthened even more, not only between states, but also between approved institutions active in the transplantation process and among states and NGOs. Information exchange about waiting lists and available organs and tissues should be enhanced in order to make transplantation systems as effective as possible and ensure their transparency. Furthermore, states should join transplantation exchange services, when appropriate, to give their citizens better chances of obtaining necessary organs, tissues or cells, especially in the case of patients for whom finding a suitable donor is difficult in smaller countries.

Organ shortage and the extreme economic disparities and inequities in access to transplantation services throughout the world are the main causes of trafficking in OTC and trafficking in human beings for the purpose of organ removal. Every effort must therefore be made to find solutions for legally facilitating the pool of available organs and preventing the above-mentioned illegal activities.

Needless to say, the promotion of organ donation must be closely accompanied by extensive information and by discussion of the issues. It goes without saying that such discussion must include psychological, ethical and religious aspects, as otherwise the public acceptance that is needed will hardly be achieved.

"Trafficking in organs, tissues and cells" and "Trafficking in human beings for the purpose of the removal of organs": need to collect reliable data

There is limited knowledge of the current situation regarding trafficking in OTC and trafficking in human beings for the purpose of organ removal. This is because little information is available from official sources, with figures and trends mostly coming from estimates and rumours. Details of the number of victims and trafficked OTC accordingly remain rather fragmentary. There is possibly therefore a high number of unreported cases in both instances. This is because of the huge profits and rather low risks for the perpetrators. Victims/donors are also mostly ashamed and frightened to report cases, recipients of organs will remain silent and the other people who know about the interventions are mostly directly involved in the trafficking offences; thus it is very difficult to investigate the crimes.

This limited data availability hinders the quantification of the two phenomena and hence the evaluation of the effectiveness of measures to prevent and prosecute them. Their qualitative description is also difficult. The data should therefore be disaggregated by sex in order to assess whether and to what extent the processes disproportionately affect women and girls because of the feminisation of poverty. With estimates that 5-10% of kidney transplants worldwide are trafficked, it is clear that trafficking in organs and trafficking in human beings for organ removal is a global issue, commonly occurring in the form of what has been defined as transplant tourism. The better known form (which does not mean it is the most common) involves travel by potential recipients from rich Northern countries to poor Southern countries where organs from local donors are transplanted. Local donors are mainly the poorest and most vulnerable members of the relevant communities. The cases described also involve local deceased organ donors whose organs are preferentially allocated to foreigners through commercial transactions.

States should make an effort to collect reliable data on both forms of trafficking. To that end, they should ensure traceability of all organs transplanted from donors to recipients and vice versa. Professionals should be encouraged also to report any such practices detected to the relevant local authorities. They should ensure proper knowledge of the origin of every single organ for transplantation and confirm that it has been obtained in accordance with international standards and local legislation.

Trafficking in organs, tissues and cells: need for an internationally agreed definition

It is clear that there are many major statements and international instruments which refer to trafficking in OTC. However, there is no single definition that has achieved international consensus. It is important to reach consensus as to the definition of trafficking in OTC for three reasons. First, enforcement of the prohibition of trafficking in OTC requires clarity with respect to the activity that is being targeted. Second, consensus about the definition is important at a time when many groups and some states are considering amending legislation and public policy to permit various forms of financial incentives and reimbursement for some forms of organ and tissue donation. Third, consensus is important since the definitions used highlight the dimensions of conduct and activities that are regarded as illicit and it is important to achieve international agreement on precisely why particular types of conduct and practices are unacceptable even though they help to reduce the demand for organs and tissue for transplantation.

The Bellagio Task Force Report on Transplantation, Bodily Integrity, and the International Traffic in Organs published in 1997 defines trafficking in OTC as follows:

> "the purchase of organs from living persons or the provision of economic incentives to the kin of deceased donors."

Article 22 of the Council of Europe *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* prohibits organ and tissue trafficking, with trafficking defined as being in violation of Article 21 of the Protocol, which states:

> "The human body and its parts shall not, as such, give rise to financial gain or comparable advantage."

Paragraph 119 of the Explanatory Report to the Additional Protocol specifies the following:

> "As stated by Article 21 of the Convention, the human body and its parts shall not, as such, give rise to financial gain. Any trade in organs and tissues for direct or indirect financial gain, as defined by Article 21 of this Protocol is prohibited. Organ trafficking and tissue trafficking are important examples of such illegal trading and of direct financial gain. Organ or tissue traffickers may also use coercion either in addition to or as an alternative to offering inducements. Such practices cause particular concern because they exploit vulnerable people and may undermine people's faith in the transplant system. This is why the prohibition of trafficking in organs and tissues is specifically referred to in Article 22."

The 2008 *Declaration of Istanbul* defines trafficking in OTC as:

> "the recruitment, transport, transfer, harbouring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation."

Council of Europe *Recommendation Rec (2004) 7 of the Committee of Ministers to member states on organ trafficking* defines trafficking in OTC as follows (Article 2, paragraph 4):

> "For the purposes of this recommendation the term "organ and tissue trafficking" applies to:
>
> – the transportation of a person to a place for the removal of organs or tissues without his or her valid consent;
> – the transportation of a person to a place for the removal of organs or tissues with his or her consent but in contravention of legislation or other controls in operation in the relevant jurisdiction;
> – the transplantation of removed organs and tissues, whether transported or not, in contravention of legislation or other regulations in operation in the relevant jurisdiction or in contravention of international legal instruments."

What is notable about these definitions and explanations is that there is a remarkable consensus that trafficking in organs and tissues is heinous, unethical and illicit. Why that is the case is not, however, reflected as a matter of consensus in these various definitions of trafficking and it is clear that the two problems, organ trafficking and trafficking in human beings for the purpose of organ removal, are confused. Despite the fact that there are some international standards that do address trafficking in OTC, mainly in the above-mentioned legally binding Council of Europe instruments, the lack of an agreed definition of organ trafficking creates a real problem in terms of identifying different situations as trafficking in OTC and qualifying as a criminal offence specific situations involving such illicit trafficking.

There is therefore a need to adopt an internationally agreed definition of "Trafficking in OTC" set out in a legally binding international instrument. Such a definition should be agreed upon at international level with the involvement of all the relevant players. While underlining that all national systems should be based on the principle of the prohibition of making financial gains with the human body

or its parts, the starting point for such a definition should be the idea that any organ transaction outside the national systems for organ transplantation should be considered organ trafficking. It is therefore recommended that an international legal instrument be prepared, setting out a definition of "Trafficking in OTC" and the measures to prevent such trafficking and protect and assist the victims, as well as the criminal-law measures to punish the crime.

Trafficking in human beings for the purpose of removal of organs: the effectiveness of existing international standards and no need for further international legal instruments

All relevant aspects for preventing and combating trafficking in human beings for organ removal are set out in the Council of Europe Anti-Trafficking Convention and in the United Nations Trafficking in Persons Protocol. Both instruments are comprehensive and cover the major issues ranging from criminalisation to assistance and protection – thereby covering the so-called three "P"s: prevention, protection and prosecution, which are essential for tackling the issue of trafficking in human beings effectively.

These instruments provide a very good basis for states all over the world to implement their provisions. By signing and ratifying these instruments, which – as explained above – set out a broad range of obligations for states on different issues and require the development of a comprehensive system of victim protection and assistance, states can show their political will really to want to combat the trafficking. As the definition of trafficking in human beings, including for the purpose of organ removal, is the same worldwide, setting up such systems in all countries would establish a sound and strong framework to prevent perpetrators from carrying out offences and enhance international co-operation, in particular regarding prosecution of offenders and victim assistance.

The problem is that not all states have signed and ratified the instruments, which leaves loopholes for perpetrators, as they can avoid higher risks and carry out their "business" in countries with less strict laws. Unfortunately, this involves a much higher risk of nationals of that state becoming victims of trafficking in human beings. But even states which have ratified these instruments and implemented their provisions have so far mostly not paid attention to the aspect of organ removal. In the international debate, this aspect has hardly been mentioned at all and many states do not consider the matter to be of great importance, as not many cases of this kind are known of in their jurisdiction. In many states implementation has therefore remained incomplete, as countries failed to pay special attention to this aspect of exploitation.

When implementing the criminal law provisions, it is important to make sure that victims are not punished for their involvement in unlawful activities connected to the crime. Additionally, the focus in implementation should be on the punishment of those individuals who exploit other individuals, their health and bodies, for financial profit, i.e. mainly brokers and intermediaries, as well as doctors, health staff and hospitals directly involved in the exploitation network. On the other hand, states should keep in mind the specific situation and vulnerability of both the donors and the recipients of organs when drafting legal provisions. They are often in situations where they see no way out but to participate in the illegal transactions.

Both the legally binding international instruments tackle all the important areas and lay down the basic rules for combating trafficking in human beings for organ removal. The measures in *Council of Europe Convention CETS No. 197* go even further, especially regarding assistance and protection for victims.

The Council of Europe Anti-Trafficking Convention [*CETS No. 197*] is a holistic instrument which does not leave any questions or needs open; its framework is comprehensive and it includes a broad range of obligations for states to implement. As mentioned throughout this Joint Study, no big issues remain open which are not already covered by the convention or require the drafting of an additional protocol or instrument, especially against the background of the convention's thematic link with the *Convention on Human Rights and Bioethics* and its *Additional Protocol*. The Council of Europe Anti-Trafficking Convention [*CETS No. 197*] must in any case be read and implemented in conjunction with the latter, as they include many provisions which are prerequisites for properly understanding, implementing and interpreting provisions regarding the purpose of organ removal (especially regarding consent). Taken together, these instruments provide not just a basis for tackling trafficking in human beings for organ removal, but a very comprehensive, strong and good one. At European level, there is clearly therefore no need for an additional legally binding instrument concerning trafficking in human beings for the

purpose of organ removal (e.g. additional Protocol to Council of Europe Anti-Trafficking Convention [*CETS No. 197*]).

The Council of Europe Anti-Trafficking Convention [*CETS No. 197*] also provides for an independent monitoring mechanism (GRETA) to monitor whether its provisions have been properly implemented and issue recommendations as to what requires special attention and which additional steps have to be taken by individual countries. GRETA should pay special attention during the forthcoming monitoring rounds to the aspect of trafficking in human beings for organ removal, i.e. making sure that this aspect is taken care of and included in national legislation as well. This is particularly important since the relevant EU *Framework Decision on trafficking in human beings* only covers issues of sexual and labour exploitation and explicitly not those of organ removal. The focus in several EU member states may well therefore have been on the sexual and labour exploitation aspects only, especially since the aspect of organ removal has hardly been discussed at all until now. In addition, GRETA will have to monitor not only whether criminal provisions cover this aspect but also whether the assistance and protection measures are suited to the purpose as well.

Other states should in any case sign and implement the United Nations Trafficking in Persons Protocol, paying special attention to trafficking in human beings for organ removal. In implementing the protocol, they should take account of the provisions included in the Council of Europe Anti-Trafficking Convention [*CETS No. 197*], as its provisions are more comprehensive and detailed than those in the United Nations Trafficking in Persons Protocol and set out even more obligations. As the Council of Europe Anti-Trafficking Convention [*CETS No. 197*] is also open to non-member states, other states could also decide to join it to show their clear and strong will to combat trafficking in human beings and be bound by even stronger commitments.

There is no need for further legal action on a global or regional level. What is really needed is strong political will to sign, ratify and implement the existing international legal instruments. Besides, if states wish to go further in some areas, they are always free to do so. However, no major issue has been left open in the existing international documents that would involve a need for any further international legal action.

Where international action is really needed is in the following areas:

Information and media campaigns have been part of international and national activities for a long time, but still remain important. The focus has been on particular types of victims (women, children) and awareness-raising, with the emphasis initially mainly being on sexual exploitation and, more recently, also on the aspect of labour exploitation. It is important also to raise awareness about the aspect of trafficking in human beings for organ removal. In this way, prevention could be improved as people were shown what kind of risks are really attached to the illegal sale of organs (especially the frequent denial of follow-up-care) and what kind of illicit means (in particular deception) are used by the perpetrators. Together with information about legal organ donation methods, this would help build trust in national health systems and could increase the quantity of organs available legally.

Improved co-operation between states is necessary, in terms both of mutual legal assistance and providing victim assistance and also of joining regional or international transplant organisations that provide for equitable allocation of organs among the states involved. Every means of combating the shortage of organs and of improving the donor pool is an effective measure against trafficking in human beings for organ removal.

Co-operation with civil society remains an important issue and should be improved, in particular as regards medical and psychological follow-up care of victims of trafficking in human beings for organ removal and as regards prevention.

As previously stated, enhanced information exchange and research is one of the major issues. It is difficult to obtain an overview of the real situation, the number of cases and victims and trends, etc. As data of this kind are necessary for the development of strategies and programmes, international organisations should strive to gather as much data as possible so as to be able to shed more light on the dark area of this crime and to tailor new programmes and initiatives to combat it.

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