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DRAFT REPORT

on Organ donation and transplantation: Policy actions at EU level
(2007/2210(INI))

Committee on the Environment, Public Health and Food Safety

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on Organ donation and transplantation: Policy actions at EU level (2007/2210(INI))

The European Parliament,

– having regard to Article 152(4) (a) of EC Treaty,

– having regard to Commission Communication on Organ Donation and Transplantation: Policy Actions at EU level, COM (2007)0275, and the Commission Staff Working Document accompanying the Communication: Impact Assessment SEC(2007)0705,

– having regard to Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[1],

– having regard to World Health Organisation's Guiding Principles on Human Organ Transplantation,

– having regard to Council of Europe Convention on Human Rights and Biomedicine, and its additional protocol concerning Transplantation of Organs and Tissues of Human Origin,

– having regard to a document from the first national expert meeting on organ donation and transplantation at Community Level, SANCO C6 EFZ/gsc D (2007) 360346, 13 September 2007,

– having regard to Rule 45 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Legal Affairs and the Committee on Civil Liberties, Justice and Home Affairs (A6-0000/2007),

A. whereas the needs of patients for transplantation in Europe are not being met and the demand has outstripped the supply of organs from both deceased and altruistic living donors,

B. whereas data is now available on the trafficking of human organs and there is evidence of rapidly developing commercialism and transplant tourism,

C. whereas safety issues are often ignored when illegal commercial organ transplantation is practiced, which may put the life of the donor and the recipient at risk,

D. whereas quality, safety, efficacy and transparency are essential if society is to reap the

[1] OJ L 102,7.4.2004, p.48.

benefits transplantation can offer as a therapy,

E. whereas there are discrepancies between Member States with respect to rates of transplant, to the source (living or deceased donor) of organs, as well as to quality and safety requirements for organ donation and transplantation, while the organisational approach to transplantation varies from country to country leading to uneven standards across the EU,

F. whereas organ transplantation provides the possibility of saving lives, of offering a better quality of life and of having the best cost/benefit ratio,

G. whereas organ donation and transplantation are sensitive and complex issues that encompass not only medical but also legal and ethical aspects, which require the full participation of civil society for their development,

H. whereas the use of organs in therapy contains a risk of transmission of infectious and other diseases,

I. whereas a number of organs are already exchanged between Member States but no pan-European organisation coordinating the exchange exists,

J. whereas public awareness and concrete and positive information have an important role to play in increasing the willingness to donate organs,

1. Welcomes the Commission Communication "Organ Donation and Transplantation: Policy Actions at EU level" for its proposed future policy actions and priorities in relation to organ donation and transplantation at the European level;

2. Looks forward to the Commission proposal for a Directive, which should set quality and safety requirements for their donation, procurement, testing, preservation, transport and distribution across the EU; stresses, nonetheless, that the forthcoming legislative framework should not create an excessive administrative burden for Member States, nor should it jeopardize the use of existing good practices; points out that the new legislative document should complement and reinforce efforts made by Member States to achieve an active and efficient method of coordination without preventing the introduction or maintenance of more stringent measures;

3. Expresses its concern over the insufficiency of available human organs for transplantation to meet patient needs; acknowledges that the severe shortage of organ donors remains a major obstacle preventing the full development of transplant services and the main challenge that EU Member States face with regard to organ transplantation;

4. Takes note of the important differences with respect to the source of organs (deceased or living donors) within the EU, the large differences between Member States' success in increasing their donor pool, the discrepancies between Member States when it comes to quality and safety requirements and the different organisational approaches

to organ donation and transplantation; considers that discrepancies can be partly explained by a combination of cultural, ethical, religious, historical and social factors; nonetheless points out that the critical factor seems to be how the whole process leading to donation and transplantation is organised;

5. Consequently, stresses that the establishment of well-structured operational systems and the promotion of successful models at a national level are of the utmost importance; suggests that operational systems should comprise adequate legal framework, technical and logistic infrastructure, psychological and organisational support coupled with an effective allocation system;

6. Calls on Member States to reach the full potential of donations by establishing efficient systems for identifying organ donors and by promoting transplant donor coordination in hospitals across Europe; asks Member States to explore the promotion of donations from living donors and evaluate the use of organs from "expanded" donors, taking into account quality and safety aspects;

7. Considers that, in the future, biotechnology may offer the possibility for researchers to grow organs from existing tissues, either from the patients themselves or from other tissue donors; asks the Commission to promote such research, which is often carried out by Europe’s emerging SME biotech companies within the cultural and ethical frameworks laid down in the Member States;

8. Points out that there is a link between organ shortage and organ trafficking; emphasises that any commercial exploitation of organs that denies an equitable access to transplantation, is unethical, is inconsistent with the most basic human values, contravenes Article 21 of the Convention on Human Rights and Biomedicine and is prohibited according to Article 3(2) of the EU Charter on Fundamental Rights;

9. Calls on the Commission and Member States to take measures to prevent 'transplant tourism', including drawing up guidelines to protect the poorest and most vulnerable donors from being victims of organ trafficking and adopting measures that increase the availability of legally procured organs; asks the Commission to promote via the Justice, Freedom and Security area a common approach which aims at compiling information on national organ trafficking legislation and to identify the main problems and potential solutions; points out to this effect that a system of traceability and accountability of human material crossing borders has to be established;

10. Endorses measures which aim at protecting donors and ensuring that organ donation is made altruistically and voluntarily, without other payment than compensation which is strictly limited to making good the expenses and inconveniences related to the donation; urges Member States to define the conditions under which compensation can be granted;

11. Takes note that, although several Member States have introduced compulsory registration of transplant procedures and some voluntary registries also exist, no comprehensive system exists to collect data on the different types of transplantation and their outcomes; strongly supports the creation of national registers of living

donors but also a post-transplant registry;

12. Invites the Commission to facilitate the development of a core of technical and ethical standards for the management of the safety, quality and efficacy of human material for transplantation that can serve as a model for Member States; asks the Commission to establish an EU mechanism which would promote coordination activities between Member States in relation to organ donation and transplantation;

13. Considers that an additional benefit of collaboration between EU Member States which is insufficiently emphasised in the Commission's Communication is the potential value of organ sharing between EU Member States; believes that organ sharing can be very helpful particularly as far as difficult transplant procedures are concerned;

14. Recognises that it is vitally important to improve the quality and safety of organ donation and transplantation; points out that this will have an impact on reducing transplant risks and will consequently reduce adverse effects; acknowledges that actions on quality and safety could have an effect on organ availability and vice versa; asks the Commission to help Member States develop their capacity in creating and developing national regulations and regulatory framework to enhance quality and safety;

15. Points out that quality improvement programmes, jointly performed by specialists in intensive care and the transplant coordinator of every hospital, should be established in every hospital where there is potential for organ donation and transplantation;

16. Emphasises that good co-operation between health professionals and national authorities is necessary and provides added value; asks the Commission to facilitate alliances between national transplantation organisations in Member States involving cooperation at legal, ethical and technical level; recognises that there are situations in transplant medicine that cannot be adequately addressed in Member States with a limited donor pool; believes that small Member States, in particular, could clearly benefit from European co-operation;

17. Considers that international co-operation to promote organ donation is desirable in order to help maximise organ donation and to provide equal access to transplantation; asks Member States to actively promote such cooperation so as to increase the access of citizens to these therapeutic procedures;

18. Underlines the importance of increasing public awareness on organ donation and transplantation since it can facilitate the identification of organ donors and thus increase organ availability; stresses that the idea of organ donation should be promoted within specific groups of population (i.e. students, teenagers, young adults);

19. Is convinced that a very effective way of increasing organ availability is to provide more information to the public also at the local and regional level; calls on the Commission, the Member States and the organisations of civil society to take part in this effort to raise public awareness of the possibility of organ donation whilst taking

into account the cultural particularities in each Member State; acknowledges that it is important to improve the communication skills of health professionals by, for instance, developing information guidelines; expresses the need for a professional attitude towards, and support from experts in the field of communication; special attention should be paid to both the content of the message and the best means of dealing with the most controversial topics;

20. Asks the Commission to support research into organ donation and transplantation across national boundaries to address the impact of ethnicity, country of origin, religion, level of education and socio-economic class on the decision to offer organs for donation; asks the Commission and Member States to disseminate rapidly the outcomes of research with a view to informing the public and altering misperceptions;

21. Acknowledges that post-transplant results should be monitored and evaluated; stresses that common methodology should be promoted amongst Member States to achieve optimal results;

22. Instructs its President to forward this resolution to the Council, the Commission and the Parliaments of Member States.

EXPLANATORY STATEMENT

Organ transplantation means therapeutic use of human organs involving the substitution of a non-functional organ for another one coming from a donor. Successful organ transplants, provided that a proper follow-up procedure is applied, can restore a full and healthy life for many years to people who would otherwise often require intensive care, which is unpleasant for the patients, but also often places a burden not only on the healthcare systems in the Member States but also on the family and carers of the patients.

Although the use of human organs for transplantation has steadily increased during the past decades across the EU, the number of people requiring a transplant is greater than the number of organs available for transplant. Nearly 40.000 patients are now on waiting lists in Western Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.

Quality and safety

The use of organs in therapy poses a risk of diseases being transmitted to the recipient. Risks include not only the transmission of communicable diseases (viral, bacterial, and fungal infections, human, immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV)) but also the transmission of malignant diseases, such as the transmission of different types of cancers.

Donor testing is important in minimising the risks to the recipient; it is essential to screen donors and establish the presence or absence of risk of disease transmission. In order to establish the standard level of donor safety, a minimum set of examinations should be performed. However, there is no consensus today between Member States on these tests.

Pre-transplant evaluation of potential donors is a vital part of solid organ transplantation. In other words, donor suitability is an essential prerequisite for donation. The main goals include: identifying conditions which disqualify donors; identifying possible pre-transplant infections and defining the level of risk in order to determine strategies for preventing post-transplant effects. The differences on screening between the living donor and the deceased donor are largely based on the different time at which this screening takes place. For the living donor it is possible to treat active infection and to defer transplant until such infection resolves. By contract the timeframe for deceased donor evaluation is typically hours. Donor suitability criteria should be established according to existing accepted medical standards. Long-term follow-up and monitoring of patients following transplants are also needed to evaluate the best treatment outcomes for patients. The monitoring and evaluation of post-transplant results is crucial and should therefore be carried out on the basis of a common methodology, which ensures the maximum health and safety standards in all Member States.

Currently, organ transplants are only followed up for around 9 months to 12 months following the transplant. Evaluation of transplant outcomes should be extended to several years, to give the best evaluation of outcomes, both clinically and in economic terms.

Organ Shortage

The severe shortage of organ donors remains the main challenge that Member States face with regard to organ transplantation. Growing waiting lists are a serious problem. More than 40,000 patients are currently waiting for a kidney in Western Europe. Waiting lists have become longer in all EU countries as well as in the rest of the world. Even in cases of sustained increases in the number of donors, waiting lists and waiting times are very difficult to shorten.

The establishment of an efficient system for identifying persons that could become organ donors upon their death, once all mandatory consent requirements in Member States have been met, is a key element in fighting organ shortage. The process of evaluation of organ suitability is a multiphase event, focused on a) the definition of acceptable-unacceptable risk of transmission of infectious or neoplastic diseases and b) the establishment of practical steps for the risk evaluation process, considering in the single case the transmittable disease, the specific conditions of the recipient with respect to the transmittable disease, the available means of prevention and the treatment of the disease.

Another important option in expanding the donor pool is considering the promotion of altruistic donations from living donors. The morbidity and mortality of patients waiting for transplantation require careful consideration of those potential donors who would normally not be considered as ideal candidates; these are called expanded donors (i.e. allowing transplants from HIV positive patients to other HIV positive patients.) When the donor pool is expanded in this way, doctors are concerned with increased likelihood of rejection of the organs and gradual decline of the function of the grafted organ. It is vital to support methods to prevent and treat organ rejection so that the expanded pool can be used with confidence by doctors. The training and employment of health professionals responsible for identifying potential donors has also proven to be useful and must be encouraged wherever resources allow it. Biotechnology is already offering solutions e.g., treatments that reduce rates of rejection, which will, in turn, support the availability of more organs, by allowing doctors to treat or even prevent rejection. This, therefore, helps support the expanded donor pool, by reducing the risk associated with expanded organ programmes. It is worth mentioning that in the future, biotechnology may offer the possibility for researchers to grow organs from existing tissues, either from the patient themselves (autologous) or from other tissue donors (allogeneic). Work to promote such research, which is often carried out by Europe's emerging SME biotech companies, should be stimulated wherever possible, within the cultural and ethical frameworks laid down in the Member States.

Organisational aspects

Organisational systems not only have an impact on quality and safety of organs but also on their availability. There are severe discrepancies in organ donation and transplantation activity within and between Member States. The different organisational systems in Europe are the result of their origin and history. Comparison between countries shows that final national donation rates do not always correlate with the percentage of people who have previously declared themselves ready to donate in these countries. This clearly indicates the importance of having an efficient transplant system in place ensuring that the organs of people willing to

donate become available.

A prerequisite for any action in this area is the establishment of an adequate transplant system at national level. Such a system requires an appropriate legal framework, which is not market-oriented, and a good technical approach as well as organisational support. The role of competent authorities is crucial in the organisational system. These authorities must ensure compliance with basic standards and organise the donation and transplantation activities. The most efficient organisational systems should be used and promoted.

As mentioned above, organ transplants are subject to time pressure. The process from procurement to transplantation should be completed in a few hours (in order to preserve organ viability). In addition, for organs to be transplanted the donor has to match with the recipient. This makes the organisational structure a key element of organ donation/transplantation systems. As part of this organisation, an effective allocation system is essential, which takes into account the short time organs can be maintained and the need to ensure that the organ is assigned to the most suitable recipient, according to predefined criteria.

Public awareness

Public awareness and public opinion also have an important role to play in increasing organ donation. Organ donation and transplantation are medical treatments that require the full participation of society for their development. Many complex and sensitive ethical issues are linked to this area, and it has become clear that several of these aspects are dealt with differently in different countries depending on the prevailing values and beliefs. These different values and concerns should remain and should be dealt with at a national level. Increasing public willingness to donate can be supported by improving the knowledge of health professionals and the media about transplantation issues. Continued education should form an important element in any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. There is a strong positive correlation between having discussed it within the family and the willingness to donate organs.

In other words, public awareness must be enhanced to the as much as possible, both through provision of adequate information upon request, and its extensive dissemination to local, regional and central communities in Member States, including, but not limited to, schools, clinics, social and community centres and churches. Additionally, in the light of the evidence that people are more willing to donate organs if they have discussed the matter first with their family, comprehensive information should be provided to the family of the donor or potential donor.

Other Issues

** Co-ordination and other activities*

Bearing in mind that there is no pan-European coordination of organ exchange, it is crucial that the existing arrangements for organ exchange between Member States are reinforced and coordinated in a more specific way in order to cover national needs and increase the efficiency of such exchanges. The existing practices should not be jeopardised nor should the

administrative burden be increased.

** Altruism*

Altruism must constitute the main element of organ donation and transplantation. The economic terminology used in the Commission's Communication is therefore not adequate, in particular in view of the principle of non-commercialisation of the human body. Therefore, the language used must not suggest, under any circumstances, that organs may be treated as a commodity of the Internal Market.

This principle of non-commercialisation of the human body and its parts is expressly stated in Article 3 (2) of the EU Charter on Fundamental Rights. The Commission Communication mentions this principle only in relation to organ trafficking. Thus, we find it crucial to stress that this fundamental principle also applies to the donation of one's own organs.

In general, ethical aspects relating to organ donations should remain within the competence of Member States in accordance with the principle of subsidiarity.

** Trafficking*

In the face of available data on the trafficking of human organs and evidence for rapidly developing commercialism and transplant tourism, it is pertinent not to underestimate organ trafficking as a secondary area of concern. It must be recognised that organ trafficking is caused by a combination of poverty and hopelessness, the desire to make a living, as well as corruption and unscrupulousness of criminals, globalisation of the economy and the exploitation of human beings. Unfortunately, in many cases, people in the East become the spare parts inventory for the sick in the West.

Cooperation with international organisations (such as EUROPOL and INTERPOL) must be pursued to combat organ trafficking both in the EU and outside its borders. Policy changes should not create further obstacles to cross-EU cooperation and cooperation with other international and European organisations, where desired.