

Organ donation and transplantation: Policy actions at EU level

European Parliament resolution of 22 April 2008 on organ donation and transplantation: Policy actions at EU level (2007/2210 (INI))

The European Parliament,

- having regard to Article 152(4)(a) of the EC Treaty,
- having regard to the Commission Communication to the European Parliament and the Council on Organ Donation and Transplantation: Policy Actions at EU level (COM(2007)0275) and the Commission Staff Working Document accompanying the Communication: Summary of the Impact Assessment (SEC(2007)0705),
- having regard to 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 cells¹,
- having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data²,
- having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector³,
- having regard to Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use⁴,
- having regard to the World Health Organization's Guiding Principles on Human Organ Transplantation,
- having regard to the 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 the Council of Europe report "Meeting the organ shortage. Current status and strategies for improvement of organ donation" (1999),

¹ OJ L 102, 7.4.2004, p. 48.

² OJ L 281, 23.11.1995, p. 31.

³ OJ L 201, 31.7.2002, p. 37.

⁴ OJ L 121, 1.5.2001, p. 34.

- having regard to the Council of Europe report "Guide to the safety and quality assurance for organs, tissues and cells"¹,
 - having regard to a document from the first national expert meeting on organ donation and transplantation at Community Level², held in Brussels on 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 (A6-0090/2008),
- A. whereas the need for organ transplantation in the European Union has increased steadily and more rapidly than the number of organs donated, whereas there are more than 60 000 patients in need of transplants on waiting lists across the EU and whereas a significant number of patients die as a result of the chronic shortage of organs, whereas the increase in the number of donors does not lead to a reduction in the waiting lists,
 - B. whereas organ trafficking, commercialism and transplant tourism, which are inconsistent with respect for human dignity, are rapidly developing; whereas there is a link between organ shortage and organ trafficking, whereas more data on organ trafficking are needed,
 - C. whereas safety issues are often ignored when illegal commercial organ transplantation is practised, which may put the life of both the donor and the recipient at risk,
 - D. whereas four Member States have still not ratified the United Nations Convention against Transnational Organized Crime, five Member States have not ratified its supplementary Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children ("the Palermo Protocol"), nine Member States have not ratified the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography, and 17 Member States have not ratified the Council of Europe's Convention on Action Against Trafficking in Human Beings.
 - E. whereas although current estimates put organ trafficking at a relatively low level among all forms of trafficking, trafficking in organs and tissues is becoming an increasing global problem which occurs within and across national borders and is demand-driven (there are an estimated 150-250 cases per year in the EU),
 - F. whereas trafficking in organs and tissues is a form of trafficking in human beings, which entails serious violations of fundamental human rights, and in particular of human dignity and physical integrity, and can undermine citizens' confidence in the legitimate transplantation system, which may lead to a further shortage of supply of voluntarily donated organs and tissues,
 - G. whereas quality, safety, efficacy and transparency are essential if society is to reap the benefits transplantation can offer as a therapy,

¹ Third edition, 2007.

² SANCO C6 EFZ/gsc D (2007) 360346

- H. whereas organ transplantation is the only available treatment for end-stage failure of organs such as the liver, lung and heart and the most cost-effective treatment for end-stage kidney failure; whereas organ transplantation makes it possible to save lives and to offer a better quality of life,
- I. whereas there are significant differences between and within Member States with respect to rates of transplant and to the source (that is to say the living or deceased donor) of organs, and even discrepancies in quality and minimum safety requirements for organ donation and transplantation, while the organisational approach to transplantation varies from Member State to Member State, resulting in uneven standards across the EU,
- J. whereas Member States have different legal frameworks (with some Member States having an opt-in and others an opt-out system in place) and experiences in different Member States show that the impact of the legal system on the number of donors is quite limited,
- K. whereas the alternative to transplantation is often intensive care, which is unpleasant for the patient and places a burden on healthcare systems and the family and carers of patients,
- L. whereas organ donation and transplantation are sensitive and complex issues that encompass not only medical but also legal and ethical aspects, and require the full participation of civil society for their development,
- M. whereas the use of organs in therapy involves a risk of transmission of infectious and other diseases,
- N. whereas a number of organs are already exchanged between Member States and different European organ exchange organisations (e.g. Scandiatransplant, Eurotransplant) already exist,
- O. whereas existing experience (for example the Spanish model, the Belgian GIFT project, DOPKI and the Alliance for Organ Donation and Transplantation (Alliance-O)) shows positive results and should be taken into account,
- P. whereas public awareness, concrete and positive information and the advanced training and communication skills of professionals have an important role to play in increasing willingness to donate organs,
- Q. whereas effective public health measures to facilitate the early detection and management of the chronic diseases that cause organ failure, such as chronic kidney disease, need to be introduced in order to minimise the number of people needing organ transplants in the future,
- 1. Welcomes the above-mentioned Commission Communication which proposes a very welcome integrated three-pillar approach;

Legal instrument

- 2. Looks 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 necessary to meet those requirements; stresses, nonetheless, that the forthcoming legislative framework should not create an additional

administrative burden for Member States or service providers, nor should it jeopardize the use of existing good practices or those practices adapted to the prevailing conditions and circumstances in individual Member States, or contain requirements which would lead to a decrease in the number of potential and actual donors;

3. Points out that the new Directive 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;
4. Underlines that the Directive should accommodate the progress made by medical science;

Co-operation between Member States

5. Expresses its concern over the insufficiency of available organs for transplantation to meet patient needs; considers reducing the organ and donor shortage to be the main challenge that Member States face with regard to organ transplantation; recalls that many thousands of patients in Europe are currently registered on waiting lists, which have a significant mortality rate;
6. Notes that the allocation of organs should be based on the medical capacity of the patient to accept an organ; is of the opinion that discrimination on the basis of disabilities which have no bearing on the patient's chances of accepting an organ should not be tolerated;
7. Points out that organ donation is a gift; therefore stresses that, while finding an answer to the severe shortage of organs in the EU is extremely important, the freedom of choice as to whether or not to donate an organ needs to be respected and protected as well;
8. Takes note of the significant differences as regards the source of organs (deceased or living donors) within the EU, the substantial differences between Member States' success in increasing their donor pool, the discrepancies between Member States concerning quality and safety requirements, the different organisational approaches to organ donation and transplantation and the differences in the education and training of medical and paramedical professionals; considers that discrepancies can be partly explained by a combination of economic, structural, administrative, cultural, ethical, religious, historical, social and legal factors, although the critical factor seems to be how the whole process leading to donation and transplantation is organised;
9. Strongly believes, therefore, that there is significant potential for sharing expertise between Member States in order to increase donor rates and equalise access to transplantation across the EU; hence, looks forward to the Commission's action plan for strengthened cooperation between Member States in order to:
 - increase organ availability,
 - enhance the efficiency and accessibility of transplantation systems,
 - increase public awareness,
 - guarantee quality and safety;
10. Consequently, stresses that the establishment of well-structured operational systems and the promotion of successful models within and between Member States, and where

appropriate at international level, are of the utmost importance; suggests that operational systems should be composed of an adequate legal framework, technical and logistical infrastructure, psychological and organisational support and an appropriate organisational structure, at hospital and supra-hospital level, equipped with highly qualified staff, coupled with clear provisions on traceability and a fair, effective and equitable allocation and access to transplantation system;

Increasing organ availability

11. Points out that Member States are responsible for their own legal models; notes that in the EU two models exist, each with different variants; considers it unnecessary to adapt or harmonise legal systems; invites Member States to adopt legislation enabling the appointment of a legal representative who can decide on donation after a person's death;
12. Calls on Member States to achieve the full potential of post-mortem donations; therefore urges Member States to invest to the full in improving their organisational system by:
 - sensitizing, educating and training medical and paramedical staff,
 - supporting hospitals financially to appoint in-house transplant coordinators (doctors working inside the intensive care units who are supported by a medical team), whose task would be actively to identify potential donors and approach their families,
 - implementing quality improvement programmes in every hospital or cluster of hospitals across the EU where there is proven evidence of potential for organ donation;
13. Asks Member States, with a view to increasing organ availability, to evaluate the use of "expanded" donors (i.e. older donors or those that have certain diseases) taking into account quality and safety considerations;
14. Considers that transplants can be carried out using a sub-optimal organ; it would then be for the transplant team, acting in consultation with the patient and/or his or her family, to make decisions about the use of organs for individual patients on the basis of a risk-benefit analysis;
15. Asks Member States allowing living donation to take into account quality and safety considerations; stresses, however, that living donation should be seen as complementary to post-mortem donation;
16. Recognises that, when the donor pool is expanded, doctors may be concerned about the increased likelihood of rejection of the organs and gradual decline of the function of the transplanted organ, and therefore asks the Commission and Member States to support methods to prevent and treat organ rejection so that the expanded organ pool can be used with confidence by doctors;
17. Recognises that biotechnology is already offering solutions to the risk of rejection of transplanted organs, for example through 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; argues that this would help support the expanded donor pool, by reducing the risk associated with expanded organ programmes;

18. Asks Member States to remove, before January 2010, legislation that reserves donor organs for use solely within that Member State;
19. Asks Member States to take the measures necessary in the areas of education and training, teamwork and remuneration of transplantation surgeons;
20. Stresses the importance of financing organ procurement and transplantation under a dedicated budget line, so as not to make transplantation a disincentive for hospitals;
21. Underlines the need to ensure that organ donations stay strictly non-commercial;
22. Endorses measures which aim at protecting living donors, from a medical as well as a psychological and social point of view, 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 strictly limited to making good the expense and inconvenience associated with the donation; asks Member States to ensure that the anonymity of deceased and living donors not genetically or emotionally linked to recipients, where national legislation permits such donations, is preserved; urges Member States to define the conditions under which compensation can be granted;
23. Urges the Member States 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; thus, donations by unrelated living donors only being permitted to be made under the conditions defined in national law and following authorisation by a suitable independent body;
24. Urges the Member States to ensure that living donors are not discriminated against, in particular by insurance systems;
25. Urges Member States to ensure the reimbursement of the social security costs of living donors;
26. Considers that, in the future, provided that traceability is guaranteed, biotechnology may enable researchers to grow organs from existing tissues and cells, either from the patients themselves or from other tissue donors; asks the Commission to promote such research, which is often carried out by the EU's emerging SME biotech companies within the cultural and ethical frameworks laid down in the Member States and in the Charter on Fundamental Rights and the Council of Europe Convention on Human Rights and Biomedicine;
27. Notes that several clinical trials in humans have proven the efficiency of adult stem cell treatment in several cell replacement therapies;

Efficiency and accessibility of transplantation systems

28. Notes that, although several Member States have introduced compulsory registration of transplant activities and some voluntary registers also exist, there is no comprehensive system for the collection of data on the different types of transplantation and their outcomes; strongly recommends the creation of national follow-up registers of living donors, transplanted patients and transplant procedures; points out that those registers must be regularly updated; stresses the importance of ensuring the comparability of the data

between Member States;

29. Asks the Commission to recommend to the Member States certain guidelines concerning registration to ensure that the registered person submits certain information about his or her medical history and to ensure the quality and safety of the donor's organs, since registration involves not only the simple act of registering by name but implies consequences for both the donor and the recipient;
30. 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 organ donation in the context of donation and 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;
31. Considers that an additional benefit of collaboration between Member States, which is insufficiently emphasised in the above-mentioned Commission Communication, is the potential value of organ sharing between Member States in terms of medical and technical opportunities, although takes full account of the geographical limitations to such exchanges and the potential effects on organ viability; underlines in this respect the positive results of international systems; believes that organ sharing can be very helpful particularly as far as difficult transplant procedures are concerned (for example in the case of highly sensitized or urgent patients and patients with special conditions, for whom it is difficult to find a suitable donor);
32. Invites the Commission, together with the Member States, to conduct a study on all matters concerning organ transplantation for non-EU residents in Member States and to develop a code of conduct setting out rules and conditions under which organs donated by deceased EU donors may be allocated to non-EU residents;
33. Emphasises that good co-operation between health professionals and competent authorities is necessary and provides added value; asks the Commission to facilitate alliances between national transplantation organisations in Member States involving cooperation of a legal, ethical and technical nature; 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;
34. Calls for a EU donor card, complementary to existing national systems;
35. Considers that international co-operation to promote organ availability and safety is desirable; points out, in this regard, that general rules governing best medical practice, diagnostic techniques and conservation would be useful; asks Member States to promote actively such co-operation and to apply this system of general rules;

Increasing public awareness

36. Underlines the importance of increasing public awareness of organ donation and transplantation in order to facilitate the identification of organ donors and thus increase organ availability; hence, calls on the Commission, Member States and civil society to enhance structurally the promotion of organ donation, inter alia among youngsters in schools; in this regard, suggests using well known personalities (for example sportsmen and sportswomen) and educational packs;

37. Points out that information on organ donation and transplantation should be provided in a transparent, unbiased and non-directive manner, addressing the scope of organ donations, i.e. that donation might include multiple-organ donations as well as tissue donations;
38. Underlines that the free choice as to whether or not to donate an organ is the exclusive right of the donor and needs to be respected, and that organ donation must be considered as a gift from one human being to another; points out that this needs to be reflected in the language used, avoiding economic terminology which suggests that organs may be treated as a commodity of the internal market;
39. Calls on the Commission to take into consideration the further development and expansion of the existing European web page on organ donation¹, as well as that of the World Health Organization (WHO)², to cover all Member States, in all official EU languages, with the aim of providing all relevant information and data on organ donation and transplantation;
40. Calls on the Commission and Member States to promote a donor day and recommends actions that underline the good results and importance of transplantation;
41. Is convinced that a highly 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, churches, religious and humanist communities to take part in this effort to raise public awareness of the possibility of organ donation whilst taking into account the cultural particularities of each Member State; underlines the important role played by registered donors in promoting organ donation among family members and friends and encouraging them to become donors themselves;
42. Acknowledges that it is important to improve the communication skills of health professionals by, for instance, developing information guidelines; stresses the need for a professional attitude towards communication, as well as support from experts in that field; special attention should be paid to both the content of the message and the best means of dealing with the most controversial topics; stresses the importance of regular meetings with media representatives to promote the good results and importance of transplantation;
43. Favours the establishment of a transplant hotline with a single telephone number which is managed by a national transplantation organisation, where such an organisation exists, and staffed 24 hours per day by appropriately trained and experienced professionals able to provide relevant and accurate medical and legal information rapidly to all actors concerned;
44. 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 that research with a view to informing the public and altering misperceptions;

Improving quality and safety

45. Recognises that it is vitally important to ensure the quality and safety of organ donation and transplantation; points out that this will have an impact in terms of reducing transplant

¹ www.eurodonor.org (and/or www.eurocet.org)

² www.transplant-observatory.org

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 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;

46. Acknowledges that post-transplant and post-donation results should be monitored and evaluated; stresses that a common methodology of data analysis should be promoted, on the basis of the best practices currently employed by Member States, in order to allow optimal comparability of results across Member States;
47. Asks Member States to increase the monitoring times for transplant patients to several years and preferably for as long as the patient lives and/or the graft still functions;
48. Calls on the Commission to allocate funds within the Seventh Framework Programme of the European Communities for research, technological development and demonstration activities (2007-2013) to promote research on better and more sensitive diagnostic techniques which will enable early and effective detection of harmful conditions such as HIV/AIDS, hepatitis and others, since an important aspect of organ transplantation is to secure safety from various detrimental factors and agents existing in the organs of the donor;

Organ trafficking

49. Points out that there is a link between organ shortage and organ trafficking, in that organ trafficking undermines the credibility of the system for potential voluntary and unpaid donors; emphasises that any commercial exploitation of organs is unethical and inconsistent with the most basic human values; stresses that organ donation motivated by financial considerations degrades the gift of an organ to a mere commodity, thus constituting a violation of human dignity and contravening Article 21 of the Convention on Human Rights and Biomedicine and is prohibited under Article 3(2) of the Charter on Fundamental Rights of the European Union;
50. Asks the Commission, in relation to third countries, to fight against the practice of organ and tissue trafficking, which should be universally banned, including the transplantation of organs and tissues from minors, from the mentally disabled or from executed prisoners; calls on the Commission and the Member States to raise the international community's awareness of this issue;
51. Considers that, in order to fight against organ trafficking in the poorer parts of the world, a long-term strategy must be adopted for elimination of the social inequalities lying at the root of such practices; stresses that, in order to combat the practice of organ selling for money (especially in countries of the developing world), mechanisms of traceability should be put in place so as to prevent those organs from entering the EU;
52. Calls 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 multiplied listing; asks the Commission to promote via the area of freedom, security and justice 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 has to be established;

53. Urges the Member States, 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; stresses that that consideration should be given to making EU citizens criminally liable for purchasing organs inside or outside the EU;
54. Calls on the Member States to take the necessary steps to prevent healthcare professionals from facilitating organ and tissue trafficking (i.e. referring a patient to a foreign transplant service which might be involved in trafficking) as well as health insurance providers from facilitating activities that directly or indirectly promote trafficking in organs, for instance reimbursing costs incurred in obtaining an illegal organ transplantation;
55. Considers that the Member States should arrange for the training of their law enforcement agencies as well as medical staff on trafficking in organs, in order to report each known case to the police;
56. Asks Member States to sign, ratify and implement the Council of Europe Convention on Action against Trafficking in Human Beings and the Palermo Protocol if they have not already done so;
57. Regrets that Europol did not come up with a survey on organ selling and trafficking because it claims that there are no documented cases; refers to reports of the Council of Europe and the WHO which give clear evidence that the organ trade is also a problem for EU Member States and asks the Commission and Europol to improve monitoring of cases of organ trafficking and to draw the necessary conclusions;
58. Asks the Commission and the Council to update the Action Plan on Trafficking in human beings and include in it an action plan for the fight against trafficking in organs, in order to enable closer cooperation among the authorities concerned;
59. Calls, in addition, for the action plan to make reference to data which are correct and verified concerning the quantities, types and origin of illegally-trafficked organs;

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60. Instructs its President to forward this resolution to the Council, the Commission, the WHO, the Council of Europe and the governments and parliaments of the Member States.