

Translation of an article published on the Italian website *Affaritaliani* on Tuesday, 23 October 2012

<http://affaritaliani.libero.it/cronache/trapianto-organi231012.html>

News

Organ transplants: more regulatory harmonisation needed

Tuesday, 23 October 2012 -15:59:00

By Cinzia Boschiero

Every day 10 EU citizens die while waiting for a transplant. Dialysis patients have a poor quality of life and little chance of survival: only 9% live for another 10 years. Those were some of the data presented by the European Commission at a recent workshop on the harmonisation of rules for organ donation and transplants. Amendments to the current European directive were also presented, as well as some up-to-date figures on the subject: in 2011, 9 604 people donated an organ in the EU 27, compared with 9 206 in 2010 and 9 152 in 2009.

The number of donors has increased slightly, but there is still a long way to go. For that reason, and to increase general awareness of the issue, the Commission organised a workshop, at which it presented some of the European cooperation projects under way. For example, 18 712 kidneys and 7 006 livers were donated by living donors in 2011. Deceased donors suffered brain death or cardiac death. Austria has the highest percentage of donors in Europe, with 42.9 kidneys donated [per million of population] from deceased persons. In Italy, there were 1 325 deceased organ donors in 2011, compared with 1 667 in Spain, 1 630 in France and 1 200 in Germany.

Andrzej Rys, Director for health systems at the European Commission, said ‘One of the projects under way is ACCORD, which aims to improve coordination of organ donations. The project started in May 2012 and will run for three years. Another project is COORENOR, which involves national organ transplant organisations. It is vital to use clear and specific language when communicating with the public so that they are well informed, for example with regard to how brain death is identified. We are also trying to train medical teams in how best to deal with donor families and organ recipients. The ‘Train the trainers’ European project is doing just that and has already trained more than 80 national coordination experts.’

Priority is given to **vigilance, traceability, correct handling of organs from selection to transport**, but above all to continual monitoring of how transparently waiting lists are managed in the various countries. Currently, only 10% of people who need an organ receive

one. On the one hand, that is because a culture of organ donation needs to become more widespread. On the other hand, citizens need to be given greater confidence in health systems and the safety of donation management. European projects aim to improve the system's efficiency, by increasing accessibility and making quicker use of the information on organs available for patients in the various Member States.

Clinical criteria, ethical standards and national legislation must also be harmonised more. The European data presented in Brussels show that doctors must be equipped to fully comply with procedures and establish the best possible relationship with living and deceased donor families. Lia Van Kempen, who gave her personal testimony in Brussels as a mother, said 'my daughter's death only made sense when her organs had been donated. She was only four years old when she fell down the stairs and lost her life. I have two other daughters, but even today if people ask me how many daughters I have, I say three, because my little one lives on in others.'

Confidentiality of donor and recipient identities applies in all Member States. What needs to be harmonised more is the system for monitoring, transferring, sending and preserving organs. More transparency is also needed in the way waiting lists are managed in the various countries. People have talked about transplants for centuries as part-science part-myth. The idea of replacing a diseased organ with a healthy one goes back to ancient times: the possibility of carrying out skin and surgical transplants was already mentioned in the Egyptian Ebers Papyrus, the Indian and Sanskrit Sushruta Samita and later in the works of the Alexandrian doctors, the direct descendants of Hippocrates. Modern transplants require various kinds of specialist, from surgeons to multidisciplinary teams, including immunologists and nephrologists. The first kidney transplant in Italy was carried out in 1967 in Rome; while the first human kidney transplant took place on 22 May 1969 in Milan.

The **Zonda transplant centre in Italy has become the country's biggest for adult and child transplants from deceased and living donors**. It has always favoured the removal of organs from brain-dead donors. That contrasts with other national and international centres, which have traditionally preferred transplants between relatives involving fewer medical or legal problems. Kidney donors can be brain-dead patients or living donors who are related to or have strong emotional ties with the recipient.

'My brother was dying and his condition was getting worse every day. I had just got married and had a young daughter', explained Sofia Ciravegna. 'The risks of living without one of my kidneys were made clear to me, but I decided to donate a kidney to my brother because I felt it was the right thing to do at that time. He also had a family and deserved a second chance at life. I admit I was afraid and so it was vital for me to have confidence in the team of doctors treating me and to get clear explanations from them about the operation and its after-effects. The scar on my body is something positive in my eyes, I do not hide it. Of course, the relationship between myself and my brother needed to be readjusted because, at first, he felt guilty towards me and in my debt. However, over time, everything returned to normal and, in addition to medical support, we received psychological counselling, which was very helpful. I would do the same again, even though I will never forget the hardest question the team of psychologists put to me before I agreed to go through with the transplant: "You

have a daughter; if you give one of your kidneys to your brother now, you won't be able to do the same for her in the future. Are you sure you want to do this?" At that moment I felt I was facing fate and life's challenges alone, but we always stand at a crossroads and must make a choice. I think I made the right choice.'

For decades Lombardy was at the forefront of transplants in Italy. However, in recent years, other Italian regions such as Tuscany and Piedmont have overtaken it in terms of the number of donors. Tuscany doubled the number of organ donations in a year by introducing the Spanish model based on transplant coordinators. Much remains to be done, also in terms of standardising the terminology used to describe transplants and organ donations throughout Europe and using ordinary as well as scientific language. Appropriate training is also needed to properly convey the meaning of brain death and, given the desperate need for organs, to dispel people's concerns about possible failure to comply with the procedures for protecting human life in all its aspects, which have been borne out by recent cases. There is misinformation and a lack of confidence in the current system.

That is why the European Commission is also organising training and information workshops for journalists, to avoid misinformation being spread in the media. Costs were also discussed. For example, the high cost of dialysis for national health services is an incentive to encourage organ donations, since the quality of life of dialysis patients is very poor. There is a European action plan for organ donation and transplantation, which all national competent authorities have signed up to. However, a more integrated system is needed to streamline procedures and shorten time frames. There are currently two European organisations for organ exchange: Eurotransplant, comprising six EU Member States [plus Croatia as well as - in a preliminary phase - Hungary too], which exchange an average of 20% of organs each year on the basis of need; and Scandiatransplant, comprising Norway, Iceland, Denmark, Finland and Sweden, which exchange an average of 10% of kidneys and 20% of hearts each year. There are also bilateral agreements, such as that between Italy and Malta, thanks to which, between 2008 and 2010, 20 organs from Malta were transplanted in Italy (kidney, heart, liver). There is also a bilateral agreement between Spain and Portugal, which allowed 41 organs from Spanish donors to be sent to Portugal in 2009. 'I had a lung transplant', said Raffaella Bruno Pinto, 'when I had two small children and could no longer breathe because of a tumour. Since the transplant, I consider life a gift to be used to help others. That is why I am happy to talk about my experience. The transplant changed me and gave me another chance to live. Today I can go skiing with my children, I can breathe as before, I can do everything again that the illness had gradually taken away from me. I will never be able to thank enough the person who gave me that second chance. Sometimes, I almost feel guilty, but I know that I carry inside me the joy of somebody who, like me, believes in the value of human solidarity.' Today, thanks to new techniques, organs, tissues and cells can be donated.

The European EFRETOS project (European Framework for Evaluation of Organ Transplantation), for example, aims to establish the conditions and methods for evaluating transplant results. It is also trying to set up a register of registers for follow-up. Donors and recipients are the two key figures in the transplant process and as such must be protected. In Italy, all stages of establishing death using neurological criteria are rigorously regulated by law and carried out by a team of medical experts (anaesthetists, neurophysiological pathologists, forensic pathologists) convened by the health directorate of the hospital, independently of possible consent for organ removal.

If a patient whose death is being established using neurological criteria meets the clinical conditions to potentially donate organs and tissue, the donor coordinator checks for any declarations by that person in the national IT system or for any document they may be carrying that expresses a clear wish to donate. We often hear about brain death, clinical death or cardiac death. However, in reality, death is death. The only difference is between the various ways it is established. That can be done using cardiac, neurological or necropsical criteria. The relevant legislation in Italy is Law No 578 of 29 December 1993 on establishing and certifying death. It defines death as the irreversible end of all brain functions. Such a condition may occur if blood circulation has stopped (flat electrocardiogram for at least 20 minutes) or if a serious lesion has irreparably damaged the brain. In the latter case, the doctors carry out precise clinical and instrumental tests. The main way of protecting organ recipients is by ensuring that the organ they receive is healthy. Organs removed for transplant are selected, irrigated and preserved under special conditions. Even organs with anomalies in the parenchyma, such as an indivisible horseshoe kidney, can be transplanted successfully. We have perhaps all forgotten about the World Transplant Games, which show that organ recipients can lead a normal, active life again.

In Italy, transplants are regulated by a series of laws, decrees, rules and European directives, which guarantee the transparency and quality of organ and tissue donations, removals and transplants. Anyone can carry out a detailed search at <http://www.trapianti.salute.gov.it/cnt/cntNormativa> by entering a date, keyword or reference to a law relating to organs, tissues or cells. It is a fundamental right of donors and their families to have their wishes respected. Only by ensuring continual synergy between the political, regulatory, ethical and European law aspects, we can improve the system and optimise the logistical and health procedures for safety and quality monitoring. In so doing, we can give fresh hope and increase awareness of medical results and targets, transparent management of waiting lists and the European transplant system.