

FOCUS ON ORGAN DONATION

More than 60 000 patients in the EU waiting for a new organ

At the end of last year there were sixty-one and a half thousand patients on the EU Member States' waiting lists for organ transplants. More than forty-two thousand of these were waiting for a new kidney, over ten thousand for a liver, around four thousand for a heart, and two thousand three hundred for a lung transplant. Many of them, however, did not have time to wait for the new organ to arrive. Deaths in the interim reduced the list by five and a half thousand.

BY ERZSEBET FAZEKAS

Managing these waiting lists (compiling them and keeping them up to date), determining the criteria for deciding who should be added to or dropped from the list and when, why and how is the responsibility of the national authorities, say the health policy decision makers in the Member States. Experts consider that only some tasks in this area can be delegated, which means that there can be no unilateral arrangement with the European Organ Exchange Organisation, for example.

If certain countries do not have a transplant programme, or have no access as yet to organs for transplant because the system is still under construction, they cannot draw up a waiting list. What is more, the fact that a list exists or the length of it are not necessarily an indication of the availability or quality of transplants, or of the satisfactory nature of supply, any more than the absence of a list means that there is no need for transplants or a short list that there is no demand, was the message that came across at the event organised by the European Commission for invited health journalists from the Member States in mid-October. They asked for our help in raising awareness of the subject and publicising organ donation at home. Those participating in the round table composed their message, summarising how they could deal with the issues of organ and tissue donation in their own work. My own intention, as I stated at the international forum, is, by examining the multifaceted aspects of this issue with the means at my disposal, to help eliminate the barriers and obstacles that can arise from ignorance, lack of information and misconception or from fear of the unknown or the grief of losing a loved one or, in some cases, from self-centredness or self-pity, even envy. As I also observed, there cannot, in Hungary, be any real cultural or religious reasons for a reluctance to allow organ procurement.

At the Brussels seminar we resolved to try to convey to others the value of solidarity – especially where someone was facing two alternatives: either to be buried with all their organs or to allow a competent surgeon in the right circumstances to remove those which at the time of death are fully functioning before they ‘expire’ and transplant them into a patient in real need to enable them to survive and enjoy a better quality of life.

THE FIGURES – IN EUROPE AND AT HOME

Most organs needed for transplant are procured from deceased donors (post-mortem). Spain has the highest proportion, with 35.3 per million inhabitants. It is followed by Croatia (33.6) and Belgium (30.1), while counting up from the very bottom of the scale we have Bulgaria (0.5), then Romania (3.6), then Cyprus (5.5). The Netherlands leads the field when it comes to living donation of kidneys for transplant (26.3). Sweden (19.6), Denmark (17.9) and Cyprus (17.3) all do well here, while Lithuania (0.9), Poland (1) and Bulgaria (1.2) struggle at the bottom. Interestingly, the most recent EU comparisons show that Luxembourg and Slovenia perform no transplants from living donors at all. It is because of this kind of situation that the EU experts are organising more seminars like the one described.

The summary data on living donor organ transplants for the EU as a whole look like this: in 2009 there were 2 855 kidney and liver transplants, in 2010 3 852, in 2011 4 100 kidney+liver transplants (4 196 if Croatia, Iceland and Norway are added).

In 2011, 20.6% of all kidneys transplanted came from living donors. This represents an increase over previous years (19.8% in 2010, 18.7% in 2009). There was no major change in liver transplants: In 2011 living donors accounted for 3.5%, in 2010 3.6% and in 2009 3.1%.

Closer to home: In 2011, the organs of 131 deceased patients were found fit for donation (a ratio of 13.1 per million). In the case of kidney transplants, the ratio of organs procured post-mortem was 20.4 per million, with 4 per million coming from living donors. According to the statistics there were 4.4 liver and 1.4 heart transplants per million inhabitants. There were no lung transplants in Hungary last year. Under a bilateral agreement, Hungarian lung transplant patients are treated in Vienna.

‘Procurement’ is managed by the European Organ Exchange Organisations such as Eurotransplant. The members of Eurotransplant (ET), forming part of this network, include along with six EU countries (Benelux, Germany, Austria and Spain), Croatia and, in the recent provisional phase, Hungary. The ET members provide one fifth (20%) of all transplant organs annually in the Member States, i.e. around 3 300 organs (2 100 taken post-mortem) and arrange for their transport. Two per cent of all organs are sent outside the Eurotransplant region or come from elsewhere. The second organisation is ScandiTransplant, which comprises three EU countries (Sweden, Finland, Denmark) as well as Norway and Iceland. 10% of the organs moving between these countries are kidneys and 27% hearts. There are also organ exchanges based on bilateral agreements. Malta sent 20 organs (kidney, heart, liver or liver lobe) for transplant into Italian patients under such an agreement between 2008 and 2010. Under an agreement between Spain and Portugal, 41 hearts left Portugal for Spain in 2009. The donor coordinators play a major role in the movement of organs for transplant, as they are responsible for the effective operation of this delicate system.

DONOR IDENTIFICATION

The criteria for the process are established according to the transplant circumstances/transplantability of the organ or organs in question (kidney, liver, lung, heart, pancreas, small bowel, combined organs). Special rules apply to transplants for children.

Identifying donors is crucial: this means recognising brain or circulatory (cardiac) death in an intensive-care patient who, owing to serious injuries suffered or other reason, is incapable of survival. The next step, ascertaining that the organ is removed appropriately from the

designated donor, is equally important. Without the active intervention of coordinators specifically responsible for transplants, any expansion of post-mortem donation is practically inconceivable. Their presence in hospitals is essential. Their role is to proactively introduce and continuously maintain donor identification programmes. Only in this way is the number of organs successfully removed likely to increase and the donation system to work better.

At the various forums, Spain is held up as a positive example: The above-mentioned 14 donors per million inhabitants ratio achieved in 1989 was increased to 33-35 within a few years, by designating appropriate coordinators. Nowadays, all Member States use donor coordinators or have completed preparations to introduce such a programme.

In 2011, a working group on "deceased donation" was set up under an EU action plan which works together with the national competent authorities and experts in the field. They have put together the necessary guidelines for setting up a transplant donor coordination network. Through the reforms introduced in this area, the donation rate in Spain has increased by 130% in ten years. In Greece, the rate rose by 132% between 2001 and 2005, and in one region of Italy (Tuscany) it doubled in the space of a year.

Today, the number of people on the waiting list is double that of operations performed. Since the survival rate of those on the waiting list is known to be poor, the experts at the Brussels seminar rightly asked how to have more donors. They ran surveys to look for the reasons why citizens might refuse donation. Of the respondents, 21% said they did not trust the donation system in general, 25% were worried that the list was manipulated and 7% had religious reasons. Confidence in the system is fragile and, once lost, very difficult to win back, the speakers emphasised. They also explained that it is actually very easy to ascertain brain death – if medical imaging shows clearly that there is no brain activity, the existence of the basic neurological criteria indicating irreversible loss of brain function can be confirmed. However, it is very difficult to get family members to accept that their loved ones cannot be brought back to life but that their organs are still viable and could be used to help someone else.

THE DONATION PROCESS

Getting the organ from the donor to the recipient is a complex process. The decision to donate in itself is not quickly or easily made. The family needs time to give its assent, even knowing that the organ has to be removed as quickly as possible. Then there are the examinations, tests, samples to ensure that the organ is not infected with the HIV virus or hepatitis, for example. Then the organ has to be preserved. The 'window' within which it remains viable for transplantation depends on the organ concerned – generally a few hours. A heart needs to be transplanted within 4 hours of removal, a liver within 10 hours, a pancreas within 12 hours, a kidney within 24 hours, a cornea within 2-3 days. Clinically speaking the single most important rule before implantation is the HLA compatibility test – without this compatibility the graft is unlikely to survive beyond 6 years. 21.6% of 2 176 rejections were caused by a mismatch. An interesting little-known fact: people who have been symptom-free for five years following treatment for a tumour, or have been found to have no recurrence of the tumour in follow-up monitoring tests for the given period, can also be donors.

Specific quality controls and registration have been worked out for each phase. As well as supervision and accreditation, organ traceability falls within national competence. Certain elements and stages fall outside the EU Directives [which are focused on "quality and safety" of organs and substances of human origin]: individual and family consent, the system of

approval, the rules for establishing brain death, waiting list priorities, the criteria for organ removal all remain within national jurisdiction.

PROGNOSIS AND TOLERANCE

Quality of life and life expectancy improve following a transplant. This is being monitored constantly in the Member States to provide the data to encourage further funding. A striking contrast to emerge is that, while the mortality rate among those waiting for a new heart, liver or lung ranges between 15 and 30%, the survival expectancy of dialysis patients is 10 years, while that of kidney transplant recipients is double (20 years).

The statistics given at the seminar show that, of 100% people starting dialysis, 78% were still alive one year later, 63% two years later, 32% five years later and only 9% after ten years.

In the case of liver transplants, the figure for quality-adjusted life years (QUALY) is 11.5. The third best result is for heart transplant patients (6.8 years), followed by lung transplant recipients, who 'gain' 5.2 years. While experts agree that dialysis is a useful treatment, they do not see it as a real solution.

Where the cost-effectiveness of living donation is concerned, the number of people coming off haemodialysis following a successful kidney transplant has meant savings of some €17 000 per patient. Seen in a different context, if the cost of medication post-transplant is compared to that of dialysis, the financial gain over a year is 84%, without even considering the benefits in terms of quality of life for the individuals concerned.

Quoting the improvements in the 2009-2011 EU transplant statistics, the Brussels experts consider that it is worth raising the bar considerably higher, because the results can be improved upon. In 2009, organs for transplant were procured from 9 152 deceased patients, whereas the number of donors rose slightly to 9 206 in 2010, then showed quite a spectacular increase to 9 604 the following year. In 2009 there were 17 886 kidney transplants (18.7% from living donors), 6 687 liver transplants (3.1% from living donors), 2 090 heart transplants, 1 418 lung transplants and 779 pancreas transplants. The figures obviously fluctuate, given that there were 18 246 kidney transplants in 2010 (19.8% from living donors) but only 6 655 liver transplants (3.6% from living donors), 1 984 heart transplants and 769 pancreas transplants. At the same time, there were more lung transplants (1 505) and 50 small bowel transplants.

2011 saw the figures rise in all areas: 18 712 patients received a new kidney (20.6% from living donors) and 7 006 a new liver (3.5% from living donors). There were 1 980 heart transplants, 1 677 lung transplants, 869 pancreas transplants and 65 small bowel transplants. Thanks to an increase in living donors, the last five years have seen a 15% improvement, the speakers reported. (In 1992 traffic accidents were still the most frequent cause of death of donors; by 2008 these had fallen dramatically, whereas strokes were still high on the list).

Despite the differing conditions and differing environments within the EU, one thing holds true everywhere: much greater potential is a given.

There could be more organs available, if Member States would only learn from each other, was the message at the seminar. The European Commission has a legal obligation to ensure high quality and safety standards.

COMMUNITY PLANS

The main objective of the EU 2009-2015 Action Plan is to increase the availability of organs, make transplants more effective and improve quality and safety. The activities of transplant coordinators, the living donor programmes, encouragement of better communication between experts and more awareness by citizens of their rights could all help to guarantee this. Register are needed to follow-up living donors and tools must be available to exchange organs from deceased donors, via international cooperation on training and cross-border organ exchange programmes – in other words, organs that cannot be used in one country must be offered to others. This means encouraging the development of bilateral contacts between the various countries, because it is lack of international cooperation that creates insularity. If we are to convince the public and allay their concerns, it cannot be emphasised enough that organs will only be sent out of the country if there are no suitable recipients at home. This has the advantage that the organ is not lost and there is a mean of taking the needs of specific patient groups into consideration and improving transplant outcomes. The adoption of such best practices can only improve results.

In the days following the Brussels seminar, the 14th European and World Day for Organ Donation and Transplantation was also held. This event, intended to highlight the importance of organ and tissue donation, was first organised in Geneva in 1996, then in 2005 [a project called EDD, co-funded by the European Union and the Council of Europe, proposed to hold] the European Organ Donation Day the second Saturday of October, in cooperation with WHO. The event gives people living with a new organ an opportunity to express their gratitude to donors and their families, the coordinators working to make organs available and the health personnel performing the operations and the follow-up care, as well as their solidarity with those still waiting for transplants. The aim of the various events is primarily to raise public awareness and bring home to individuals how much good they can do by consciously arranging in good time for organs or tissues to be used to help a seriously ill person to have a better and longer life, rather than taking them with them to the grave.

[added by the European Commission in the English version of this article]