

SEMINAR

ON DIVERSE STRATEGIES FOR FIGHTING AGAINST ORGAN SHORTAGE IN EUROPE:

Organisational and Ethical Questions



Organised within the framework
of the “Etats Généraux on Bioethics”



Main conclusions

Presented by Michel Doucin, Ambassador for Corporate Social Responsibility and Bioethics, and Ms. Yvanie Caillé, Development Director of Pierre and Marie Curie University and a member of the Advisory Council of the Agency for Biomedicine during the closing session held on 6 May 2009 and attended by Jean Leonetti, Chairman of the Steering Committee of the Etats Généraux on Bioethics, Dr. Maurizio Salvi, Secretary General of the European Group on Ethics of the European Union Presidency and Ms. Emmanuelle Prada-Bordenave, Director General of the Agency for Biomedicine.

This version has been revised by the authors, who have added references to the speeches delivered by the two Ministers, Ms. Bachelot-Narquin and Mr. Kouchner, and the Director General of Health, Mr. Houssin. Full proceedings will be published within the next few months.

In organising this seminar together with a host of eminent partners, including the French Agency for Biomedicine and the French National Commission for UNESCO, the Ministry of Foreign and European Affairs and Pierre and Marie Curie University aimed to bring a fresh perspective to the Etats Généraux on Bioethics by focusing on what is being done in countries with similar cultures and values to our own but with different practices. Organ donation was chosen as the theme because it reveals wide discrepancies in results with respect to a simple criterion - the number of lives saved.

This improvised summary, drawn up jointly by its two authors just minutes after the discussions ended, will most certainly be incomplete and we apologise to those whose presentations are not reflected in a sufficiently accurate manner or are not adequately highlighted.

Current situation

First of all, this seminar offered an opportunity to **take stock of the indications for and success of organ transplantation, as well as the extent of the organ shortage in France**. The Minister of Health and Sports, Ms. Roselyne Bachelot-Narquin, offered a wide-ranging review of the current situation in her speech to the seminar: “In France, nearly 14,000 people are awaiting an organ transplant and barely one-third of them will eventually receive one. 222 patients died in 2008 because they did not receive a transplant in time. **In Europe, nearly 400,000 patients are currently on waiting lists**. The 15% to 30% mortality rate of patients awaiting a heart, liver or lung transplant justifies a major effort to increase the opportunities for transplantation. (...) The success of organ transplantation and the ageing of the population are increasing the demand.

Dr. Bernard Loty rounded out this alarming picture by discussing the Agency for Biomedicine’s very precise data. The number of deaths that could have been prevented by transplantation is underestimated because patients are taken off the waiting list when their condition is considered to have deteriorated to the point where they could not survive a transplant procedure. Their deaths are therefore not included in the count. Much progress has been made in 10 years thanks to the efforts of the Etablissement Français des Greffes and then the Agency for Biomedicine, which Ms. Bachelot-Narquin, along with other participants, commended. “I wish to emphasise the crucial role played here in France by the Agency for Biomedicine, which has the complex task of overseeing the fair allocation of organs via the transplant teams. (...) Despite the fact that the number of transplants has increased by over 40% since 2000, the gap is widening between the number of transplants performed and the number of patients needing a transplant. (...) The shortage now prevailing is unacceptable.”

The need for transplants is increasing faster than progress in organ procurement and the charts show the two curves clearly diverging. For reasons related to epidemiology, population ageing and increasing incidence of a number of pathologies and because transplant medicine is highly effective as a treatment and its indications are expanding, the number of transplant candidates is growing. For example, the indication of liver cancer now accounts for 13% of liver transplant candidates. And needs are almost certainly underestimated as a result of self-censorship, because doctors refrain from placing their patients on the waiting list when they feel that the hope of obtaining a graft is too slim.

This situation is not limited to France: in Europe as a whole, 65,000 patients are waiting for a transplant (one in four is French), with 25,000 transplants performed and 5,500 deaths due to lack of organs every year.

A proven technique

The effectiveness of transplantation is obvious in the case of organs such as the liver, heart and lung, for which there is no alternative; it enables patients who would otherwise die to survive for long periods of time with good quality of life. But as Professor Michèle Kessler, head of the nephrology unit at the Nancy university hospital, demonstrated, it is also a highly effective treatment in the case of kidney disease, where its superiority to dialysis is indisputable. Apart from offering much higher quality of life, a kidney transplant **substantially increases patient life expectancy** compared to dialysis. Life expectancy is increased by a factor of 2.5 on average, and by up to 3.8 when the organ received is “perfect”. Dr. Christian Jacquelinet reported calculations made by the Agency for Biomedicine demonstrating that in addition to the benefits to the individual patient, transplantation also offers the advantage of being more cost-effective for society at large.

The most telling calculations relate to kidney transplants. Expanded use of the procedure has generated substantial reductions in health care spending compared to the alternative treatment, dialysis.

3,000 kidney transplants save 90 million per year in dialysis costs, i.e. 1.7 billion euros over a period of 10 years,! Each additional increment of 500 transplants generates savings of 15 million per year. The figures are impressive and could justify the use of additional resources to optimise organ procurement at a time of health budget deficits.

But ultimately, and most importantly, the difficulty in obtaining access to transplantation is an issue of equality with respect to the right to health care and, more broadly, a human rights issue involving the right to health, dignity and life.

Against this backdrop, there is an obvious need for more efficient strategies to support increasing use of transplantation. The Minister called on participants to review all the strategies and listed the main ones: “Strategies that **broaden the range of donors** by expanding the use of **organs from living donors and donors who died of cardiac arrest**; strategies that strive to **optimise organ procurement by better organising the identification of potential donors**, improving the transport of organs and teams and **allocate the organs in the most useful way possible**.”

These avenues were explored at the seminar, which paid particular attention to the experience of our European neighbours as described by 10 specialists from six countries. These individual reports shed extensive light on the discussions.

Outlook for organ procurement from brain-dead patients

To start with, since the broad majority of organs are now obtained from **brain-dead patients**, ways to optimise the identification of these potential donors were explored. Dr. Patrick Jambou, a coordinator at the Nice teaching hospital, spoke about the crucial importance of involving all health care personnel and of general awareness raising going well beyond organ donation specialists. The “Donor Action” programme has proven remarkably effective, as outstandingly illustrated by experience in Nice.

Organ procurement is a public service mission of hospitals and a national priority (according to the Bioethics Law of 2004), but not all hospitals appear to perceive it as such. Some 10 hospitals in France do not procure organs at all. The role of the public authorities was mentioned in this context. The introduction of incentives, some of which already exist, and above all of sanctions where there are unacceptable situations or insufficient results, were mentioned as relevant options.

The diversity of hospital practices, together with epidemiological considerations, results in very wide regional disparities in organ procurement. And since the distribution of patients awaiting transplants is not itself uniform, long waiting lists occur in some areas while, conversely, other areas are self-sufficient and see no need to step up their procurement efforts. The result is that shortages vary from one place of registration to another, raising issues of equal access to the public health care system, in the context of the 2004 law, which in principle reinforced the concept of equity with respect to the distribution of organs to patients awaiting transplants. This state of affairs should prompt an effort to achieve more equitable geographical distribution of organs. Dr. Axel Rahmel discussed an innovative experience, Eurotransplant, a foundation located in the Netherlands that organises the implementation of rules governing the distribution of available organs across a vast area covering the Benelux countries, Germany, Austria and Slovenia. This reinforces equity among patients and combats shortages more efficiently.

The goal of this seminar was to propose a European approach to organ donation, and the Spanish example was therefore of course a special focus. Spain is the world leader in post-mortem organ procurement (35 pmp versus 25 in France) and exports its model to the rest of the world. Dr. Caterina Delveccio presented the way in which the Italian National Transplant Centre, starting from a very low level, managed to transpose the Iberian method with great efficiency and effectiveness.

One of the most important steps in a procurement programme is indisputably approaching the family of the potential donor. This fundamental mission involves more than simply “asking relatives about any opposition to organ donation expressed by the potential donor during his or her lifetime”. It consists in talking with and supporting families under the best possible conditions at a particularly distressing time for them and, when it appears possible to do so, asking family members whether the deceased had ever expressed opposition to organ donation.

The discussions showed that the quality of this attention and support, in addition to being a moral and human duty, is a key element in the success of the programme. Dr. Marty Manialich, responsible for Spanish TPM (Transplant Procurement Management) training, has shown that it is imperative that this

difficult task be undertaken by professionals specially trained for the purpose. Death must not, under any circumstances, be treated as routine. It has always been accompanied by rituals and in our secularised times people want rituals, including new ones. The rapid spread of cremation – which now account for 28% of ceremonies and will soon, according to surveys, account for 50% – is a sign of the rapid change that is under way, which has also brought about a different view of the mortal remains of the deceased. Improved attention to families by coordination departments should also be seen as one form of these new rituals and the quality of the relationship with families will determine the increased use of transplantation in our country.

Organ procurement coordination must cease to involve non-professionals and must no longer be improvised.

In her speech Ms. Bachelot-Narquin called for progress in France in **“training health care professionals, rigorously and efficiently organising organ procurement and raising public awareness and providing information on organ donation and transplants (...) in order to increase transplantation activity.”** Clearly, additional efforts made in this area will foster a reduction in the refusal rate, which has remained flat in France over the last 20 years at around 30%, a level double that of Spain.

Optimisation

If more transplants are to be performed, better use must be made of available resources. Prof. Christophe Legendre, head of the kidney transplant unit at Necker Hospital, discussed the increased use of so-called **“suboptimal” kidneys**, i.e. those with one or more risk factors affecting the success of the transplantation. Results for this type of transplant are clearly less favourable, but the use of such graft is acceptable, given the shortage of organs, as long as patients are informed and give their enlightened consent. By the same token, at a time when 20% of patients awaiting a kidney in France have already received at least one prior transplant, the extended survival of transplanted organs, which requires optimum monitoring of transplant patients and improved immunosuppressive strategies, is an essential factor..

Brain death is an invaluable source of organs for transplant but it is highly limited. Dr. Philippe Tuppin, of the Caisse Nationale d'Assurance Maladie des Travailleurs Salariés, demonstrated that the maximum annual number of potential donors of this type is about 4,000 and that 11,000 would be needed to meet demand. This being the case, the use of other sources is indispensable, as the Minister pointed out.

Solidarity through organ donation by living donors

One such source would be expanded use of **living donors**, at least insofar as the kidney is concerned since the risk to the donor is very small (estimated at one death per 3,000 procedures worldwide; the Agency for biomedecine does not report any death in France) and all international studies carried out show that the outlook, including the long-term outlook, for donors is very reassuring.

Moreover, the results of this type of transplant are substantially better (the half-life of a kidney transplanted from a living donor is about 20 years, compared to 13 in the case of a transplant from a deceased donor), which should also be a major consideration in discussing this issue. Prof. Christian Baudelot, a sociologist as well as a living donor himself, discussed organ donations in general and organ donations by living persons in particular, as well as the relationship with the body. He described the way in which societal and medical changes are driving the trend toward expanded use of transplantation. He also called for recognition of the “right to a transplant” as a corollary to the right to health care.

Dr. Julio Pascual Santos of the nephrology unit at Ramon y Cajal Hospital in Madrid discussed the difficulty, especially for young patients, of obtaining a graft in Spain despite that country's unrivalled success in organ procurement from deceased donors. The difficulty has prompted Spanish decision-makers to make a pro-active effort to expand kidney transplants from living donors, based on the view that the two methods are complementary.

Dr. Per Pfeffer of Rikshospitalet in Oslo discussed Norway's experience. About 40% of kidney transplants in that country are from living donors; the practice has been in widespread use in Norway for several decades. Dr. Christian Hiesse of Hôpital Foch in Suresnes offered a quantitative and qualitative overview of the practice in Europe based on the work of the EULID Group, which stressed the fact that France is lagging far behind many of its neighbours in this area.

The 2004 Law broadened the pool of potential living donors to include the parents of recipients as well as, by way of a waiver, the recipient's son, daughter, spouse, siblings, father's or mother's spouse, grandparents, uncles and aunts, first cousins and any person providing proof that he or she has lived with the recipient for at least two years. Nevertheless, kidney transplantation from living donors is getting off to a slow start in France.

There were only 222 transplants from living donors in France in 2008 (accounting for 7.5% of all kidney transplants), whereas in the United Kingdom there were 914 and in the Netherlands 411.

A study carried out by the Agency for Biomedicine among kidney transplant teams, presented by Jean-François Lamy, shows that cumbersome organisation and lack of resources are often identified as the reasons why the number of such transplants is so low in France. Furthermore, the consequences of the unequal distribution of organs, mentioned above, also has an effect, with virtually all French living donor activity concentrated in the regions where it is most difficult to obtain kidneys for transplant.

France (together with Portugal) remains one of the very last European countries to prohibit the "paired exchange" technique, which consists in allowing a cross-donation between two donor-recipient couples when donation is impossible within each couple due to incompatibility of blood type or for immunological reasons: the donor of couple A gives a kidney to the recipient of couple B and vice versa when there is a paired compatibility. Prof. Willem Weimar, head of the nephrology unit at Erasmus Medical Center in Rotterdam, presented the experience of the Netherlands. He also explained how "altruistic" donors could offer one of their kidneys anonymously to patients who would always remain strangers - a system used in several countries including the Netherlands. 40 such transplants were carried out in that country between 2000 and 2008 (with 112 volunteer altruistic donors having registered).

Donation by living persons would seem to represent a real opportunity, but it must under all circumstances continue to be driven by solidarity alone. Against a backdrop of growing demand for organs, there is a potential temptation to set up a form of organised market under the oversight of the State, which could select, pay and monitor living donors, with the latter no longer motivated by altruism. Dr. Sadek Beloucif, an anaesthesiologist and intensive care specialist at Avicenne Hospital in Bobigny, discussed the ethical and moral limits that this type of organisation would very quickly come up against, and took the opportunity to call for safeguarding the fundamental values underpinning organ donation in our country.

Organ procurement from non heart beating donors

The last avenue the Minister asked the seminar to explore as a way to fight organ shortages was **the use of non heart beating donors**, who died of cardiac arrest. The procedure is still in its early stages and implementing it is a complex undertaking in France, as Prof. Lionel Badet, a surgeon at the Hospices Civiles in Lyons, demonstrated, but the technique is already widespread in a number of other European countries. The examples presented show the diversity of practice and perception. The criteria for death are clearly defined and shared across Europe, but the way in which proof of death is provided varies from one country to another. Dr. Jose Ramon Nunez, a surgeon at San Carlos Hospital in Madrid, discussed the practice in Spain, where 10% of transplants are from this type of donor, with the rate going up to 60% in some cities, such as Madrid and Barcelona. The United Kingdom, as Dr. Eric Chemla of Saint Georges Hospital in London showed, takes a more specific approach since heroic measures to prolong life are completely banned by law, so that organs are procured when treatment is discontinued.

The presentations underlined the clear-cut potential of this type of organ procurement as well as the ethical issues it raises. The issue of discontinuation of treatment, in particular – which is the main source of organs in some countries, but which is excluded from the French protocol for the time being - could be discussed, since this specific situation is not provided for in the Leonetti law.

Xenotransplantations are regularly a focus of attention and should be mentioned. Transplanting animal organs into human beings could be another way to help solve the organ shortage, provided the results are satisfactory. Research in this field, reviewed by Prof. Gilles Blancho, has made substantial progress but numerous and complex obstacles remain to be overcome. The outlook therefore remains remote.

Ultimately, the participants arrived at the fairly widespread view that **there is currently no simple, single solution** to the organ shortage either in France or in other countries and that as Ms. Bachelot-Narquin suggested, **the answer lies in pursuing a broad range of avenues**, keeping in mind the fact that hundreds of lives are threatened every year in our country.

The steadily increasing demand for organs has also led to the abusive practice, which fortunately has still not taken hold in France, of “**transplant tourism**”, as an act of desperation by people to whom no hope has been held out of a transplant within a reasonable period of time. Dr. Moglie Le Quintrec of the nephrology unit at Foch Hospital in Suresnes presented the results of a recent study of French residents who paid for transplants carried out abroad under conditions that are not within the law. The practice is still marginal today (just a few cases annually) and almost always involves patients who have a link with the countries concerned. Prof. Jacques Belghiti, head of the liver transplant unit at Clichy Hospital, rounded out the picture by reviewing transplant tourism worldwide. This abusive practice is a misguided way to address the failure to deal effectively with organ shortages. The best way to prevent such practices is to make a maximum effort to combat shortages and thereby offer satisfactory solutions to patients awaiting transplants.

The complex consent issue

A thorny question lay at the heart of all the discussions at the seminar: the issue of **consent**. Many different views were offered. The possibilities range from strict application of presumed consent (i.e. recognition of the absence of opposition) to explicit consent with a register of acceptances with exclusive effect. Prof. Robert Carvais, a professor of law at the University of Paris I, explained how legal experts find it difficult to strike a balance between protecting the individual (the donor) and defending public health. In remarks delivered at a reception for the seminar organisers and foreign guests, the Minister of Foreign and European Affairs, Bernard Kouchner, summed up the issue as follows: “Two rights are at loggerheads: the right of the deceased, whose freedom is extended to rejection of solidarity; and the right of the patient, a person in danger, calling for solidarity to fulfil his or her right to health care.” Presumed consent is seen by some as a form of compulsory social solidarity. Dr. Elisabeth Lepresle gave a philosophical view of donation as a new form of social contract, while Prof. Marc Grassin on the Institut Catholique de Paris highlighted the various cultural, sociological and religious paradoxes that underlie most objections to donation.

There is a temptation to change the ways in which consent is identified in order to facilitate acceptance or provide for more formal consent, and many speakers highlighted the considerable risks that a change of this sort entails and the probable consequences of such a change on organ procurement: the countries in which consent is subject to formal procedures are those where refusal rates are highest. Prof. Jean-Louis Touraine, MP for the Rhône, who moderated one of the round tables, sees organ donation as a natural form of solidarity which should be based on presumed consent, analogous to the requirement to help a person in danger. Many participants agreed with him that presumed consent expresses the choice of a society based on solidarity that focuses on the moral dimension of organ donation and the vital assistance to be provided to patients, while respecting the individual’s freedom to refuse. Minister of Foreign and European Affairs Bernard Kouchner had called, in similar terms, for “the development of a sense of solidarity which should take precedence over selfishness, which is often rooted in unconscious fears. We must convince our fellow citizens that their freedom is enhanced when they choose to give another person the most precious thing in the world, the gift of life.”

Last but not least, many speakers called for an improvement in the methods used to inform the public and raise awareness. The Director General of Health, Prof. Didier Houssin, said that “public information and awareness of the issue of organ donation, and in particular of the procedures applying to consent, must be a priority in strategies aimed at combating the shortage of organs. These are serious and sensitive issues and a climate of trust must be established with the population, because without it, organ procurement and transplantation would not be possible.” And he concluded by stressing that “the question of strategies to deal with organ shortages must be approached holistically, while respecting the gaps or tensions between attitudes and behaviour and between theory and practice. This means that we must address the issue in scientific, medical, technical, organisational and ethical terms.”

That was, indeed, the purpose of the seminar.

in partnership with the **Agency for Biomedicine**
with the support of the **René Descartes University,**
National Academy of Medicine,
Espace Ethique de l'Assistance Publique
– Hôpitaux de Paris,
MACIF Prévention,
les Entreprises du Médicament (LEEM),
les Laboratoires Astellas et Baxter
and Demain la Greffe,

and also the participation of members
of the Parliamentary Office for Scientific
and Technology Assessment

