National Consultative Ethics Committee for Health and Life Sciences

OPINION n° 115

Ethical issues in connection with organ harvesting and donation for transplanting

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Introduction

The issue of organ harvesting for transplanting — or organ donation as it is often referred to — can be broached from several angles, some of which are not altogether compatible.

For instance, people talk of organ donation "promotion" in a "scarcity" context — which sounds like the language used when speaking of consumer goods — but the sale of organs is excluded. Article 16 of the French *Code Civil* guarantees the primacy of the individual and the **non patrimonial nature of the human body**. As a consequence, the human body cannot be the subject of any commercial transaction[1].

It is true that society as a whole is fundamentally attached to the **principles of organ donation** and of the body not being treated as though it were property. However, it cannot be denied that simply appealing to solidarity and altruism falls short of the aim to provide for all those who are in need of a transplant: very many people in a precarious state of health are on the waiting list for months, sometimes for years, and some of them die because no organ becomes available in time to save their life[2].

In order to mitigate this distressful situation, but also to optimise the organisation of the organ harvesting and transplant process, legislators have set up a legal framework which raises some as yet unsolved ethical issues, such as those connected to the circulation of recipient and donor information, or to reservations and reluctance on the part of families and also of healthcarers.

It goes without saying that organ harvesting and transplanting is not a simple operation: it requires complex **organisation** ranging from coordination of hospital teams to organ transfers, not forgetting contacts with donors and recipients, nor the action of agents participating in the action upstream, such as medical emergency teams, fire-fighters, mobile hospital facilities, etc., without which organ transplant would not have been developing as successfully in the last thirty years. This organisation, which can still be improved, implies certain responsibilities and can be aided or impeded by social and cultural representations of the human body and of death.

Scientific and technical progress in the field of transplants[3] and successful outcomes in the past thirty years have had, as a direct consequence, an increase in

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[1] It could even be said that the body cannot be shared: it is "the only object which cannot be shared even if one is willing". Donation may be an option, but sharing is not.

[2] Slightly more than 400 people in France in 2009, according to the Biomedicine Agency.

[3] Lung transplants have increased in number by 200% since 2003 and by 18% between 2008 and 2009, with improvement in the post-graft survival rate (figures supplied by the Biomedicine Agency in BiomédecineMag, n°7, September 2010).

demand. To these factors must be added the impact of an increase in the prevalence of chronic diseases such as diabetes and an ageing population. Unless prevention intervenes, "the demand" for organs can only continue to build up faster than "the supply".

Increasingly, transplant rejection is being controlled more and more successfully and possible transplant survival time, which was less than two years in 1967, is now, for example with kidneys, in excess of twenty-five years,. But with each technical step forward, new ethical issues arise, in particular issues regarding information, both before and after the transplant procedure.

This Opinion will only be discussing organ transplants, such as kidneys, livers, hearts, pancreas and others. The grafting of tissues or cells raises ethical issues of other kinds, so that such cases will be mentioned only in passing.

1. Because in the main members of the community know very little about the conditions in which organs are donated and also because of the distortion between harvesting practices and legislative documents, there is a need to consider, first of all, the issues which have been the subject of legislative regulation but which continue to raise discussion: in particular the **issue of consent**, depending on whether the transplant is harvested *post mortem* or is the gift of a live donor.

2. Secondly, this Opinion explores the possibilities for **improving the organisation of the process, harvesting on the one hand and transplanting on the other**, by focusing on the problems raised by hospital coordination and the dissemination of information on the conditions for organ donation.

3. Thirdly, using this current situation as a starting point, there is a need to consider how **society as a whole views donation, transplants and death in the case of deceased donors**. How, for instance, can we arrive at acceptable information policies on the subject of transplantation, while taking due account of the social and cultural representations of the body, body integrity and death?

1. Methods of consent

Consent is always required before donation, but the procedure differs depending on whether donors are deceased or live. France, just like Spain, was committed almost from the start to preferring deceased donors: in France, 70% of the deceased person's relatives, when they are asked, reply that he or she would not have objected. In Spain[4], the proportion is 85%. In contrast, only 9.7% of donations in France in 2010 were

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[4] Dr.Miranda, M.D., working at ONT (*Organisation Nationale de Transplantation*) underlines that in 1999, there was an increase in the number of deceased donors over the past ten years of 15 to 32 pmp (per million inhabitants) in Spain. In France, the figure is 22 pmp.

between live donors, while other countries such as Norway have a public health policy which gives preference to live donors over *post mortem* donation.

1.1 Post mortem consent and donation

The 1994 and 2005[5] bioethics laws, as they are referred to, are based on the same principles as those adopted by the 1976 law (the "Caillavet[6]" law) which regulated organ donation.

As regards cadaveric donation — which should preferably be called **"*post mortem* organ harvesting"** for the simple reason that dead people cannot donate — the law states that organs can be removed as long as the persons concerned did not make it known in their lifetime that they objected to the procedure. This is what doctors and hospital co-ordinators need to find out, by consulting the refusals register kept by the *Agence de la Biomédecine* for that very purpose and, if the deceased's name is not to be found there, by seeking information from the deceased person's family. It should be noted that many people are unfamiliar with the text of the law[7] so that they refer to "presumed consent".

In practice, however, if the family objects to organs being removed, some surgeons prefer not to oppose the family's wishes, although they are under no legal obligation to comply. It sometime happens in fact that family objections outweigh the deceased person's own intentions, even when a donor card expressing consent to organ

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[5] The 1994 and 2004 laws detailed special situations such as underage donors and qualify transplantation as one of the national priorities.

[6] Law n°76-1181 dated 22nd December, 1976. Published officially on December 23rd, p.7365.

[7] **Art. L. 1232-1. – Organ removal from a person whose death has been duly recorded can only be performed for therapeutic or scientific purposes.**

Removal may take place providing the person has not, while still living, made it known that he or she objects to such removal. The objection can be expressed in any form, in particular by recording it on a nation-wide computerised register kept for that purpose. The decision can be revoked at any time.

If the physician has no direct knowledge of the will of the deceased person, he must attempt to obtain from the deceased person's family information regarding opposition to organ removal which may have been expressed by the person concerned while still living, by any means available, and inform the family of the end purpose intended for the organ that are removed.

The family is informed that they are entitled to know which organs are removed.

The *Agence de Biomédecine* is advised, before the procedure, of any removal for therapeutic or scientific purposes.

removal was left by the deceased. Although it can be argued that overriding the family's objections may be seen as a form of violence against them, it must be said that practitioners are duty bound to inform them that their opposition is not legally enforceable.

The legal system puts families in a quandary. They must express their approval or disapproval to *post mortem* organ harvesting but must not be expressing their own wishes. It is not their own opinion which is being asked for; they are asked whether they know of a possible objection to the procedure which may have been voiced by the deceased person. However, in the immediate aftermath of a person's death, objection to organ removal expressed by family may, initially, rest entirely on apparent or fleeting reasons directly connected to feelings experienced in a moment of bereavement. **The shortness of time**, due to technical concerns related to the conservation of organs if they are to be transplanted, enters into conflict with the requirement that the bereaved be granted some respite. The family may feel the need for more time than is given them. In any event, be it those members of the family who are opposed to organ removal for reasons that deserve respect, or those who consider that organ removal is what the deceased would have wanted, they must be helped to come to terms with the situation.

1.2. Legislative documents and practices

The system based on an absence of opposition, which those who inspired the 1976 law saw as a humanist presumption of collective solidarity, conforms with the principle of the non patrimonial nature of the human body and is intended to spare the bereaved family from having to take a painful decision.

And yet, whenever the law is reviewed, its legitimacy is questioned, in particular because of the health caring professions' attitude, which introduces a distortion between the law and what they practise when they choose not to disregard family objections. This distortion, which is relatively rare in bioethics, since the medical professions are generally very respectful of the law, deserves further attention:

Some currents of opinion consider that, to respect entirely the spirit of solidarity inspiring the Caillavet law, *post mortem* organ removal should be all but automatic, with the human body becoming a collective resource in the service of sick people, except and unless the deceased person had expressly formulated objections during his or her lifetime.

Others are in favour of a system in direct opposition to implicit consent, in which those who do not express an opinion are in fact refusing to donate their organs, in the name of respect for the human body and of active and conscious solidarity. Clearly, with such a system, the immediate consequence would be to reduce drastically the possibility of organ retrieval.

Is there a middle road between these two extremes? Some members of CCNE would be in favour of the possibility, while retaining the refusals registry, of expressing by means to be determined, explicit consent to organ removal. After all, this would go no further than implementing the donor card across the board, a system which is not widely known. In the absence of any expression of opinion one way or another, organ removal would still be allowed, as the law currently states. This system, which could lighten the burden on some families, is not favoured by healthcarers who fear that when the deceased person's wishes are not known, medical teams would be in doubt as to whether they can, or cannot, harvest organs[8].

In conclusion, the only method that ensures compliance with the law while sparing the feelings of families, is for them to be informed of the donor's wishes during his or her lifetime.

This is the spirit in which the various formulations proposed by the *Agence de la Biomédecine can be interpreted*, this one for example: *"Organ donation: donor or not, I know for my loved ones and they know for me"*.

1.3 Living donors and social ties

Living donor transplantation is relatively uncommon in France. Several reasons combine to explain this fact. Medical advances with the help of *post mortem* removal have added substance to the notion according to which, all the *post mortem* possibilities must be explored before a healthy person is approached with a view to living donation. There are, of course, certain emergencies — some lung transplants for example — where living donation is the only chance of saving a life. Even when there is no immediate danger, if a close relative chooses entirely independently to donate a kidney to a loved one in need, this should not be discouraged, not just because it will improve the sick person's quality of life, but it will also benefit the life of the couple or of the family as a whole.

Living donation is only allowed after certain procedures defined by law have been completed. One specific aim is to ensure that the donor is not subjected to any pressure. But there are situations (for example, between parents and children or between spouses) where excessive insistence on the part of society to limit donation would be considered intolerable[9]. Nevertheless, although free and informed consent is not an alibi, it must be examined in the light of the collective responsibility of the medical team and of the authorities, the latter being instructed by both the 1994 and 2004 laws to verify the donor's autonomy, in the persons of the presiding judge of the *Tribunal de Grande Instance* (regional court) and a committee of experts.

As a first step, consent is expressed in the presence of the presiding judge of the *Tribunal de Grande Instance* who makes sure that consent is free and informed and

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[8] When the subject was discussed in the French Parliament in May, 2011, Mme Jacqueline Fraysse proposed an amendment which was not adopted.

[9] Véronique Fournier, *Le bazar bioéthique*, Robert Laffont, 2010, p.30: "The procedure has now become so cumbersome that it seems almost dubious. As though the medical world and society as a whole felt somewhat 'guilty' of not complying with the sacrosanct principle of *primum non nocere*, and therefore sought vindication".

that the donation conforms to legal provisions[10]. Consent can be revoked until the very last minute, i.e. up to the time when the organ is harvested.

The committee of experts' task is to authorise organ removal, verify that the information the medical team provides to the donor is complete and pertinent and finally, to make sure it was fully understood. This information includes the risks and consequences for the donor's own health, the chances of success or failure for the type of transplant procedure concerned and how the recipient's health status is likely to develop without a transplant. This assessment of the information is of the utmost importance for the donor, but is an extraordinarily difficult task for the committee. How, for instance, can the committee be certain that donors are not concealing their lack of understanding because of their determination to proceed with the donation?

At each step in the procedure, the donor's possible vulnerability is evaluated as well as the quality of motivation.

On this point, it must be emphasised that donation is the materialisation of a bond rather than the transfer of property. Taken in isolation, the concept of donation is an abstraction: it becomes effective when the social bond encompassing the act of giving is taken into account.

Certain thinkers, Marcel Mauss[11], for example, speak of a trilogy: **to give, to receive, to give back.** It is true that it is no easier to receive than to give, because he who receives is under an obligation, is indebted, and needs or must give back, even if there is no legal obligation nor any demand for restitution: *"As giving is an ambition and a prerogative, accepting is submission"*[12]. Furthermore, the recipient may feel an obligation of success. There must be social restitution to avoid submission following a gift received. Donation, to some extent, is reciprocity.

Organ donation is particularly burdensome in that it expresses a need and responds to a vital necessity. To enjoy "*more freely and joyfully that which is borrowed*" [13], enjoyment must be "*neither an obligation nor a constraint*" [14] and only if one can do without. Which is not the case for organ donation. Therefore the donation must be related to the reality of a social bond, otherwise the gift is no more than an abstraction to

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[10] In the event of a life or death situation, consent is obtained, by any means available, by the *Procureur de la République* (public prosecutor).

[11] *Essai sur le don*, 1925, reprinted by PUF, 2007.

[12] Montaigne, *Essais*, III, IX, p.969, PUF, Éditions Quadrige, 2004.

[13] Ibidem.

[14] Ibidem.

which high principles (altruism, solidarity, generosity) are added without the benefit of greater clarity.

The relational nature of organ donation does not simply reside in individual decisions and the awareness of the action of giving. This is a circumstance in which misappreciation of the gift is beneficial to both donor and recipient: "***There is no contractual obligation to give back,*** *the donor never fully apprehends the meaning of what he is giving, the recipient ignores in part the meaning of what he is receiving and does not know when, how and to whom he will and/or must give it back*"[15].

2. Organising organ removal and transplant: what is the optimum?

The transplantation process is a chain in which every link is important: one team prescribed the indication and, more often than not, will be monitoring the recipient patient. There is the team which harvests the transplant and the team which performs the transplantation. There is a committee of experts when the organ is the gift of a living donor, the hospital co-ordinators for *post mortem* organ removal, the team determining brain death, the health security governing medical action aimed at the deceased person or with the health status of both donors and recipients. Transplantation is not therefore confined to one single medical department as is the case for critical care: it is provided by a continuum of services and care and commits the collective responsibility of the medical professions and society as a whole.

2.1. The waiting list and organ availability

We have found that the extension[16] of the list of possible living donors given in the 2004 law, which until then was limited to family members of the first degree of kinship, has not in fact yielded any significant increase in the number of living donors. Initially, the extension aimed to remedy what has been dubbed 'the shortage' of organ donation. This concept of a shortage really means inadequacy or imbalance between the number of available organs and the number needed. Since this **imbalance** appears to be increasingly structural, as the success of transplantation leads to an increase in the number of requests, extending the list of possible donors does not appear to be sufficient to solve the problem.

The **annual number of deaths** in France, meeting the requirements of both definitions, i.e. 'brain death' on the one hand, and death determined after persistent cessation of the heartbeat and respiratory function on the other hand, would be

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[15] Anne-Marie Fixot, « *Don, corps et dette : questions anthropologiques et philosophiques, une approche maussienne* », *in Donner, recevoir un organe, droit, dû, devoir*, directed by Marie-Jo Thiel, Presses universitaires de Strasbourg, 2009, p.115.

[16] "Spouses, brothers and sisters, sons and daughters, grand parents, uncles and aunts, first cousins and the spouse of the father or mother may be authorised to donate an organ for the direct therapeutic benefit of a recipient. The donor may also be any person able to prove he or she has been cohabiting with the recipient for at least two years".

sufficient — if all of these deaths were recorded and the organ retrieval teams were made aware of them in good time — to supply a number of functional organs just about adequate to cope with the need for transplants for patients whose state of health required them to be put on the waiting list on a given year[17].

And yet there is no denying that the number of organs harvested, anatomically and functionally suitable for transplanting, turns out to be far less than what is theoretically possible and, therefore, very inadequate to satisfy the current year's transplant needs[18].

Since the number of organs retrieved is clearly smaller than the annual number of new requests on the transplant waiting lists, these lists cumulate the number of requests in previous years that could not be satisfied and the year's new crop of requests. As a result, the relative number of people on the waiting list grows faster than the number of available organs and there is a growing shortfall of organs and a longer wait for those needing a transplant. With respect to end stage renal failure, however, in order to avoid any possibility of conflict of interest, the dialysis team should not be tasked with putting patients on the waiting list. The list should be **made open to patients at an early stage** so that they can benefit from the best chances of obtaining a transplant at a time when it can still change their lives positively and sustainably.

The discrepancy between the number of available organs and the number of people on the waiting lists grows inexorably. Patients dying while they are on the lists is a regular occurrence, particularly as regards single organs or the lungs. Organic deterioration, connected to the pathology which made a transplantation advisable, is such that **after too long a time spent waiting**, the outcome of transplantation becomes doubtful. At this point, the procedure ceases to be a rational indication, despite the persistent pleas of the patients concerned, who do not always evaluate with precision the risks, possibly life-threatening, which they are incurring.

This also happens with patients receiving repetitive haemodialysis for renal insufficiency who have had an excessively long wait for an organ to become available to them.

As regards the transplanting of single organs such as the heart and liver, going onto the waiting list depends on a medical indication which requires truly informed consent on the part of the patient concerned. The benefit/risk ratio must be explained with great care and the failure of palliative treatments for the pathologies affecting these organs must be proven, since the functional failure of these organs is known to be lethal in a very short time in the current state of the art of palliative treatment. Here again, however, "early" arrival on the list could help to reduce the number of deaths while patients wait.

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[17] This would be an approximate equilibrium every year, without taking into account the possible shortfalls of previous years.

[18] And even less, obviously, those which could not be performed in previous years.

As regards the transplanting of organs for which functional substitution can be achieved with artificial devices, for example, the kidneys, the pancreas, the lungs (and more recently the heart since the advent of implantable artificial hearts), the current situation of delayed inclusion on the waiting lists should be taken into account. Before the time when functional substitution becomes a necessity, the referring physician should be able to refer the patient to the appropriate transplant centre so that whatever tests will be necessary can be performed without further delay and inclusion on the waiting list can take place at an early stage, before even any substitution treatment begins, in particular for the kidneys (and in any event, before the start of dialysis).

In all cases, inclusion on the list of potential recipients should be **regularly revised** (every six months or annually) by the transplant centre physicians so as to check that intercurrent complications involving other organs are not threatening to render transplantation excessively risky.

In order to shorten waiting times and improve the general state of health of potential recipients when they are about to receive a transplant, an upgrade of the independent management of waiting lists by the transplant surgeons would seem to be absolutely necessary.

As regards living donations, the 2004 law defined possible donors. Some opinion groups criticised the very concept of a list since it could suppose certain exclusions and some degree of arbitrary decision: why should a son-in-law not be allowed to donate a kidney to his mother-in-law or father-in-law, for example? Why should, as is the case currently, two close friends be prevented from donating organs to each other? A "proven, emotional and lasting bond", to use the phraseology favoured by associations seeking to develop living donation, served as the basis for discussion in parliament when the bioethics laws were being reviewed. The version adopted on second reading by the French parliament refers to "any person able to prove the existence, since at least two years, of a close and stable emotional bond with the recipient". The two year stipulation is to avoid the possibility of abuse in the form of the recruitment of paid donors claiming to be close to the recipient.

Another issue is that, as all transplant surgical teams are well aware, there is a degree of geographical unfairness in the distribution of organs taken from deceased people and available for transplanting: how could waiting lists be managed more equitably?

Because of the inevitable proximity required between critical care services and the teams specialising in maintaining mechanical ventilation and assisted blood circulation combined with medical treatment of cadaveric organs, the relative number of available organs for local and regional recipients varies considerably from one area to another. **In spite of the centralisation of data** and of distribution criteria within the *Agence de la Biomédecine* (ABM), the limited time available for the conservation of organs once they are removed makes it advisable to perform the transplant without too much delay, so that distribution on a nation-wide basis is not easily arranged, particularly for hearts, livers, lungs, the pancreas and even kidneys. As a result, many histocompatible organs for recipients in the Paris area, where the greatest number of patients awaiting a transplant reside, are transplanted locally with less satisfactory histocompatibility criteria. It would however be ethically dubious, or even unfair, to lengthen for that reason the waiting time for patients living outside the Paris area and included on the lists of university hospitals around the country. Transplant teams should consult on this issue, under the aegis of ABM, to arrive at more equitable solutions.

As regards living donors, encouragement from next of kin to donate an organ (or part of an organ: liver, lung) could reduce the number of patients on waiting lists.

It is a known fact that the short, medium and long term outcomes of organ transplants from living donors are considerably more favourable than is the case for cadaveric transplants (the functional quality of the transplant, less need for high doses of immunosuppressive drugs, better quality of life, etc.).

French law authorises organ donation within a family, originally the nuclear family, but since 2004 more extensively from genetically related family members (male or female cousins, uncles and aunts).

Donation between spouses has also been authorised recently in France. However, it may turn out that a total absence of shared antigen histocompatibility within the couple, requiring potentially more aggressive immunosuppressive treatment, makes transplanting more difficult.

For this reason, lawmakers decided — this being the main innovation in the new version of the bioethics law — to authorise, between couples of donors/recipients with immune system problems that could only be overcome with extreme difficulty, a so-called “**paired-exchange**” which can be used to improve compatibility between donors and recipients in each couple.

The two surgeries are scheduled simultaneously since, up to the last minute, one of the donors may claim the right to back out, as the law authorises. The two couples are kept anonymous from each other.

With a view to optimising donor/recipient compatibility, an extension of the paired-exchange involving just two couples to an exchange involving “n” couples is being practised in the United States. This makes perfectly simultaneous procedures much more difficult to achieve, but **donor/recipient matching** is of better quality (which increases the likelihood of transplant survival).

To overcome this new difficulty and desynchronise the harvesting and transplant procedures (for the kidney in this instance) it was suggested that a **supplementary donor**, a spontaneously volunteering Good Samaritan, could be added to the group so that all the couples are certain of access to the transplantation they so dearly yearn for. This chain of solidarity, of which it can be said that it breaks the bond of donation to some degree, obviously demands very strict anonymity.

This system opens up the possibility of extending donation opportunities to people who are in no way related, which could be a problem if the principles of anonymity and total absence of compensation were not respected. In any event, the possibility could not be entertained in France until the paired exchange donation procedure, *stricto sensu*, between two compatible couples , has been put to the test.

2.2. The role of hospital coordination

Several reasons[19] have been put forward to explain this “shortage” of donated organs: refusal[20] expressed by the deceased person’s family in 30% of *post mortem* donation, the limited number of living donors, the ban on paired exchange donation, etc. But, increasingly, it would seem that the management of each of the steps in the procedure leading to transplantation is the crucial factor. Such **steps** are the initial contact with the family of the deceased, or the monitoring of living donors, or again transplant transfer as well as the conditions in which organ harvesting can be performed and in particular the essential coordination required between resuscitation and transplantation units. Medical emergency services and hospital administrations must be a fully integrated part of the management plan so that those who are willing to donate an organ to alleviate the sufferings of potential recipients can be confident that their trust is well placed.

It would seem therefore that the problem has evolved slightly: the emphasis put on **improving the 70% acceptance score** on the part of family in the case of *post mortem* harvesting or on increasing the rather low number of living donations, had distracted attention from the notion that it might also — and perhaps above all — be necessary to optimise each and every step in the organisation of transplants. Seeking to lower the 30% refusal rate can lead to a form of psychological or economic pressure: psychological if the dialogue leading to the family’s decision tried to be overly persuasive; and economic if organ donation were to be associated with some kind of financial reward for the hospital or medical teams harvesting the organ, which is out of the question in France.

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[19] The number of organ donors in Spain has dropped from 34.4 per million inhabitants in 2009 to 32 in 2010. This is the sharpest drop recorded in 20 years. The number of transplantations has also fallen (by 6%), as it was 4,028 in 2009 and 3773 in 2,010. The main reason for this decline is the drop in the number of “brain deaths” in resuscitation units, which is itself a consequence of the sharp fall in the number of road accidents. In 2009, people injured in road accidents represented 8.3% of donors as compared to 5.7% in 2010. Another factor is the reduction in the number of deaths connected to the acute phase in strokes. Nevertheless, Spain is still very much in the lead as regards the number of donors per million inhabitants, which is 18.3 in the European Union and 25.2 in the United States. As reported by the British Medical Journal (BMJ 2011;341:d242). For Germany, another issue of the BMJ noted: Germany has 12,000 patients entered on waiting lists for transplants and every year, 3,000 of those on the list die. Two thirds of the population are in favour of organ donation, but only 14% are donor card carriers. To improve this situation, a law is under preparation in parliament to the effect that all German citizens requesting an ID card, a driving licence or taking out life insurance must make their wishes known as regards organ donation. (BMJ 2011;342:d660).

[20] When he was heard by the Committee, Patrick Jambou, doctor anaesthetist, organ transplant procurement coordinator for the South-East region, remarked that the 30% were not in fact the reason for the “shortage”. In the PACA (Provence-Alpes-Côte-d’Azur) region, in 2005 the count was 13 pmp. In 2011, the figure had progressed to 27 pmp and this is due to better hospital coordination.

Healthcarers[21] are, in a way, **a magnified reflection of society**. They entertain the same doubts as other members of the community so that improving coordination between different hospital teams would certainly be worthwhile. When for example, the resuscitation team fails to bring an individual back to life, they should include in their check-list and keep in mind the idea of *post mortem* medical procedures and report the death to the organ procurement coordinators. The specialist team who maintain functional organ survival can then take over and, in compliance with public health legislation, perform the “medical procedures” on the brain dead donor which ensure that the harvested organs or tissues will be of sufficiently good quality to increase the chances for successful outcomes to transplant.

2.3. The role and function of information

Information, in this particular case, flows in two directions:

1) It is directed both at the family, in order to secure the statement that the deceased person was “not opposed” to organ removal, and at healthcarers to have them understand that they must assist the deceased person’s loved ones at the time of organ removal and in the days following this procedure. Organ harvesting after brain death can benefit, or even save the lives of, seven people with chronic diseases. No one is any longer in doubt that transplanting a kidney is much less expensive for the community than continuing dialysis, nor that quality of life with a functional transplant bears no comparison to life under the burden of dialysis. **Transplant recipients speak of being reborn.**

We also need to remember the part played by the emergency services (*SAMU/Service d’Aide Médicale d’Urgence*) and fire-fighters in the case of organ collection *post mortem* or after cardiac arrest[22], where their action may be of paramount importance. Without the *SAMU*, which is a hospital on wheels, many of the *post mortem* retrievals would be impossible. This involvement of a new category of healthcarers (the *SAMU*), raises a clear ethical issue: the vital intercessory role played by the hospital’s mobile units for the transplant’s outcome to be successful. Although these intercessors help to increase the number of transplants that can be performed, their involvement also demands that ethical vigilance be intensified. Often, the shortage of time (in particular in the event of cardiac arrest) requires that these healthcarers be better trained and

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[21] The European Parliament and Council directive of May 19, 2010, underscores the importance of the quality and safety of medical practices: “Member States shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as referred to in the Article on Quality and Safety”.

[22] Decree n° 2005-949 dated August 2, 2005, made no modification to the conditions in which death was declared, but authorised organ retrieval (kidneys and liver by virtue of an Order of the same date, text N° 53) from deceased persons in a state of persistent cardiac or respiratory arrest. But the decree leaves it to the *Agence de la Biomédecine* to set the protocols, situations and conditions in which such retrieval is to be performed. The Agency reports, as of December 31, 2007, 43 kidney transplants harvested from cardiac arrested donors. Donors were from categories I, II and IV of the Maastricht classification exclusively, see infra 3.3.

informed to interact appropriately with loved ones. The cardiac arrested harvesting technique is fairly recent, as we have already observed. In the event that it becomes more widespread, then both medical and non medical carers working with the *SAMU*, and also fire-fighters, must be trained on the subject of organ conservation and retrieval for future transplant purposes. And finally, a major problem needs to be tackled: how does one go about convincing a deceased person's loved ones that the body must be transported to the hospital for another person's benefit?

2) The donor's family needs to be informed to the fullest possible extent: just mentioning the possibility of organ removal is inadequate. Information must also be provided regarding the purpose of *post mortem* medical procedures and on the tests for safety required in order to verify that the future transplant is not carrying a disease. Participation in the process of agreeing to organ removal, which may perhaps save a life, can help some mourners come to terms with their loss if they see the event as life continuing in a different fashion. It is also important that the donor's family should be told, in particular, that there are medical criteria for transplant selection which cannot be evaluated until after the organ has been removed. A family discovering that the harvested organ was not transplanted, if they were not previously aware that this might be the case, may well feel rejected and the incident can contribute to generating among the public a sense of hostility to the principle of *post mortem* organ harvesting.

3. The body and death at the heart of the donation

3.1 Death certificate

The French Code of Public Health[23] lists **the criteria for brain death**, that is irreversible cessation of cerebral activity. These criteria establish the conditions in which authorisation for organ or tissue removal is allowable. They do not in fact coincide with what the public at large sees as being evidence of death. For a doctor, brain death is simply death, but for the lay public generally speaking, there is the notion that insofar as there is evidence of breathing (albeit artificially supported) and the body is warm, then the person is not altogether dead. This was even one of the arguments used in Japan[24] from 1968 to 1997, to put a stop to organ removal after brain death. On the contrary, sudden cardiac arrest when it occurs outside a hospital is a violent shock for the family who tend to consider their loved one is obviously dead whereas the doctor is hesitant regarding a resistant cardiac arrest, in particular regarding the time elapsing before resuscitation on which depends the irreversibility of cerebral activity.

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[23] Articles R.1232-1 and following. Decree n° 96-1041 dated December 2, 1996, states the circumstances in which a person can be pronounced dead. It distinguishes on the one hand death by persistent cardiac and respiratory arrest, and on the other, "brain death" when breathing and haemodynamic functions are maintained artificially.

[24] Cf an article by Pr. Kazuya Kondo, adjunct professor at Kanagawa University, "*The organ transplant law of Japan - the past, the present and the future*", *in* International Journal of Bioethics, 2005, vol.16, n°1-2, p. 91-102.

It is important that the idea that there are several kinds of death[25], is not allowed to gain ground in the public mind, even though it is quite clear that death can be defined in multiple definitions rooted in metaphysical or anthropological concepts. It is incorrect to state that the French Code of Public Health admits several legal definitions of death. In fact, it considers two ways of observing death, depending on whether it is brain death or cardiac death, but in both cases, the person is legally dead.

But the fact of death does not obviate the complex situation in which doctors and *SAMU* staff find themselves with regard to the deceased person's family: what should be said and how should it be said? The relatively short time available between the doctor's observation, his conclusions based on what he has observed and what he must explain to the family puts him in a position where his statement is both important and difficult to utter. In a dramatic death scene situation, in particular after the 'failure' of resuscitation, the doctor must almost simultaneously pronounce the person dead and take care of those for whom this announcement brings grief.

Added to these quandaries is the ethical difficulty of accepting that **death can be a source of life.** Some people put forward the idea of collective solidarity so that death can be "serving a useful purpose". Others see in organs being removed a form of amputation, of encroachment on the body's integrity. Those who are inclined to favour cremation (28% of French funerals and over half of the French population approves of it) confuse physical integrity and absence of mutilation. Physical integrity is in fact an absence of personal injury, the primacy and inviolability of this principle being enshrined in Article 16 of the Code Civil, but is in no way related to the presence or absence of an organ. Consider breast amputation of cancer patients and, for that matter, all those who underwent surgery because of cancer: their bodily integrity in legal terms is not disputed. We must note that **the body is neither a set nor a provider of organs.** Successful transplants do not necessarily imply a mechanistic vision of the human body as a mere assembly of spare parts. Donating an organ remains, as we have already noted, related to a social bond wherein is transmitted what cannot be shared: the body.

On the whole, society reacts variously, favourably or otherwise, to organ donation, be it after brain death or between living donors and recipients, based on several factors:

1) The first factor consists of the negative recollection of ill-fated cases, which can temporarily halt donation. For example, the first heart transplant after brain death, in Japan, in 1968, was of no benefit to the recipient who died very soon after surgery. As a consequence, this therapeutic procedure ceased to be attempted for thirty years and was

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[25] It is worth noting here the medical directives issued by the Swiss Academy of Medical Sciences, in *Diagnostic de la mort dans le contexte de la transplantation d'organes (diagnosis of death in the context of organ transplants)*, dated June 20, 2005: *"Divergent beliefs and semantic misunderstandings continue to give grounds for controversy, both as regards the general public and professional healthcarers. Expressions such "brain death" and "cardiac death" wrongly give the impression that there are different kinds of death and that "brain death" occurs before death itself. This uncertainty is further aggravated by the fact that for certain patients, some biological functions continue to be artificially maintained by mechanical ventilation and devices to keep blood circulating. For this reason, although they may be dead, these patients still exhibit some of the traditional signs of life (such as warm body, pulse, breathing apparent in thoracic movement)".*

only reintroduced very gradually because the same procedure was largely successful everywhere else. In France, in the 1980s, there was the instance of the two deaths of a completely healthy donor brother and of his sister, the recipient, following a toxic graft rejection episode. As a result, healthcare professionals suffered an emotional block and were deterred from continuing. And yet, scientifically speaking, the effectiveness of a form of medical treatment and statistics cannot be evaluated on the basis of a single case.

2) Furthermore, death gives rise to different approaches. The **determination**[26] **of death** is established on the basis of total absence of consciousness and of spontaneous motor activity, loss of all brainstem reflexes, and total absence of spontaneous respiration. In the case of people under mechanical ventilation, an examination verifies the irreversible nature of encephalic destruction. In the case of cardiac arrest, clinical reality is the root of the expression "persistent cardiorespiratory arrest".

3.2 Non-beating heart donation

Non-beating heart donation[27], i.e. donation after cardiac death came about as the result of technical progress. For quite a long time, it was only conceivable to take organs from people whose hemodynamic functions were being artificially preserved. When the heart stopped beating, all organs were destroyed and were therefore useless for transplant purposes. This is no longer the case, but only if organ preservation procedures are initiated within minutes of death, which supposes the presence of medical teams at the time of death. From 2005 onwards, non beating heart donation was authorised in France[28], but it is less frequent than donation after brain death. Outcomes with this type of donor have improved in various countries, such as Belgium, the Netherlands and Spain. In absolute values there were 39[29] cases in France in 2007 and 88 in Spain. But numbers are small compared to the total number of donations.

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[26] Cf. A. Tenaillon, *Éthique et prélèvements d'organes sur donneurs décédés après arrêt cardiaque*, *in* Médecine/Sciences, N°3, volume 26, March 2010. The 1996 decree sets out the precise conditions of death in the event of organ removal.

[27] NHBD : Non heart beating donation. Brain death is in fact a "beating heart" situation.

[28] Decree dated August 2, 2005. As a result of the joint effects of fewer car accidents and a drop in the number of trauma-induced brain deaths, the government opted for this new possibility.

[29] 62 in 2009 and 2010. This type of donation may represent in France up to 15% of total grafts for kidneys, liver and lungs, according to Alain Tenaillon, member of the Steering Committee of the French Agence de la Biomédecine. It represented only 2.4% of cadaveric donations in 2007, according to J.C. Tortosa in *Questions d'éthique soulevées par les deux types de protocoles de prélèvements d'organes à cœur arrêté*, (Ethical issues raised by the two types of protocol for non heart beating donation) in Médecine/Sciences, n°2, volume 26, February 2010.

One of the ethical issues raised in this context could be formulated as follows: would the technical ‘comfort’ offered by this new type of donation be likely to increase the risk of turning the human body into a social resource created by death? Some people are concerned, in particular, in the case of non beating heart donation, about the need for invasive procedures — which by definition can do no harm in the circumstances — on the body of the dead[30]. They begin immediately after a person is pronounced dead but before relatives have a chance of saying whether the deceased had in fact objected or not to organ removal and donation. They are intended to improve the quality of the organ that the medical staff hope to harvest. However, this technical intrusion at the crucial last opportunity of being with the person who has just died can appear as lack of respect owed to the human body after death. Other opinions, however, insist that this gift can be seen as a bond with the dead and that the procedures do not encroach on the dead person’s integrity. As regards these two different positions, the crux of the matter seems to be not so much the invasive procedure itself before the family can approve or disapprove, but more the way in which the body is considered. If there is no suggestion at any time that a body is viewed as a collection of available organs and if it is made quite clear, on the contrary, that the donation constitutes a valuable bond, the technical conditions for its preservation in the event the organ can be used are not regarded as an unacceptable intrusion[31].

The number of non beating heart donations grows apace in some countries, for instance in Spain and the United States. Some people see this as a positive step in the direction of progressing beyond the notion of brain death. In order to avoid semantic misunderstandings and controversy on the definition of death, the wording used in France now is no longer “non beating heart donor”; it is to be replaced by “donor deceased *after* cardiac arrest” [32].

3.3 The Maastricht categories put to the test of non beating heart donation

In 1995, having regard to the scarcity of the number of organs for transplant from potential donors after brain death, transplant surgeons working in the Maastrich university hospital published the results of transplants using organs harvested from individuals who had died as a result of irreversible cardiac arrest[33]. Their results were

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[30] Between 18 and 55 years of age.

[31] David Le Breton, «*Nulle société humaine ne perçoit le corps comme un cadavre indifférent après la mort* » (There is no human society which is indifferent to a body after death) *in* « Greffe », *in Le dictionnaire du corps*, directed by Michela Marzano, PUF, 2007, p.417.

[32] DDAC (donneur décédé après arrêt cardiaque) according to the Agence de la Biomédecine’s formulation.

[33] Kootstra G, Daemen JH, Oomen AP: Categories of non-heart-beating donors. Transplant Proc. 1995;27:2893-4.

not very different from those arrived at using "brain dead" donors so that there was a recommendation to make more use of this innovative method which increased the availability of organs.

In parallel, the authors defined the circumstances of irreversible cardiac arrest they had encountered and defined four different situations which are now referred to as the Maastricht criteria for "donors deceased after cardiac arrest" or "non heart beating donors".

Maastricht categories I to IV define cardiac arrest situations as either controlled or uncontrolled. Uncontrolled arrest situations, be they brain deaths or non beating hearts, give rise to organ procurement. These are categories I, II and IV. Category I refers to cardiac arrest taking place outside a hospital with delayed emergency assistance. Category II is cardiac arrest in the presence of qualified and immediate assistance, but where attempts at resuscitation failed. Category IV refers to a patient in a hospital, in a state of brain death whose heart ceases to beat when ventilation and massive solute perfusion combined with appropriate medication are initiated. Categories I, II and IV are said to be uncontrolled cardiac arrests.

It is therefore only category III which is controlled: this is the cardiac arrest of a hospital patient occurring following a decision to withdraw treatment. Organ retrieval in these cases is not recommended in France and the *Agence de la Biomédecine* has not drawn up protocols for these circumstances.

The particular case of Maastricht category III is a justifiably sensitive subject. The substantial ethical issue it raises is the reason for the absence of organ procurement since the existence of such a classification could give rise to fears that life support is withdrawn in order to obtain an organ. Category III "which, in certain countries... is the largest source and the easiest to organise, is not on France's agenda at the present time", says professor Christian Cabrol, "so as to avoid any confusion between a decision to withdraw treatment and the intention of harvesting an organ"[34]. The idea that **intention to harvest** could be associated with the motive to withdraw treatment is sufficient to motivate a continuation of the *Agence de la Biomédecine's* current cautious approach.

The law dated April 22, 2005 on the subject of patients' rights and the end-of-life, known as the Leonetti Law, gives particular emphasis to queries regarding the Maastricht category III. The second sub-paragraph of Article L. 1110-5 of the Code of Public Health, stipulates that treatment "*should not be continued out of unreasonable obstinacy. When it appears that it is futile, disproportionate or has no other object than prolonging life artificially, it may be withheld or discontinued*".

Treatment may be discontinued at the request of the patients if they are able to express themselves (article L. 111-10 of the Code of Public Health). Furthermore, and according to article L. 1111-13 of the same document, "*when individuals in an advanced*

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[34] Christian Cabrol, *Rapport au nom du groupe de travail sur les transplantations d'organes. Prélèvements d'organes sur donneur à cœur arrêté*, (Report on behalf of the Working Group on organ transplants. Organ collection from non beating heart donors) Académie Nationale de Médecine, Paris, March 6, 2007.

or terminal phase of an irreversible and serious disease or condition, whatever its cause, are unable to express their wishes, the physician may decide to limit or discontinue treatment which is futile, disproportionate or with no other object than prolonging life artificially," subject to compliance with a collegial procedure, to a proxy or next-of-kin being consulted and after referring to the living will or advance directive, if there is one. The main objective of the law is clearly to act in the best interests of patients, not to allow for the protection of organs that may be of benefit to someone else.

Patients continuing to receive palliative care, may in certain cases survive for a considerable time after treatment is discontinued. Some people believe that in the near future we may expect an increase in the number of patients suffering from irreversible brain damage, but a decrease in the number of brain dead patients[35].

When the person concerned requests a curtailment or discontinuation of treatment, or even when the physician takes this decision, the major issue is still the following: in such circumstances, should organ removal be made lawful or should it not? How does one deal with the heavy burden of decision on the shoulders of an intensivist who, in certain circumstances, may be able either to maintain the patient in a vegetative state or allow that same patient to drift towards brain death? The question only arises very exceptionally, but acceptance opens the door to serious abuse. This is exactly the situation where a form of technical advance is a prompt to lawmakers for a redefinition of the conditions for exclusion from Maastricht category III.

The law dated April 22, 2005 provides a framework at this point to make some progress in the ethical debate on the possible access of category III to organ removal. It does not, however, confer legitimacy on such a course. It must be recognised that there is a necessary preamble to this ethical debate: raising awareness regarding this law and its objectives. The law remains widely unknown, even among members of the medical professions. In the name of prudence, it would be preferable to ensure that what the law permits is fully understood before allowing developments in the direction of opening it up to possibilities regarding organ removal, for which it was not originally designed.

Recommendations

1) **Give much wider circulation to information** on the legal conditions for *post mortem* harvesting and encourage people to make their wishes known to their relatives so that they may be expressed with more certainty when relatives speak to hospital coordination teams in charge of organ removal.

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[35] The Agence de la Biomédecine requested a report on extracorporeal circulation or cardiopulmonary bypass (CPB) from a team directed by professor Bruno Riou. Their report was published "*Recommandations sur les indications de l'assistance circulatoire dans le traitement des arrêts cardiaques réfractaires"* (Recommendations on the indications of circulatory assistance in the treatment of resistant cardiac arrest) in the Annales Françaises d'Anesthésie et de Réanimation, 28 (2009) 182-186, with the object of "Proposing indications and contraindications for circulatory assistance in resuscitation for intra and extra hospital occurrences of resistant cardiac arrest".

2) Maintain a **clear separation between the resuscitation teams** — whose sole concern must be the patient's best interest — and the **organ harvesting teams** whose arrival on the scene is part of a secondary phase, after death is pronounced, and who must also ensure that the body is restored to as presentable a state as possible after organs have been removed.

3) **Improve intra- and inter-hospital communication** on the circumstances of death which may have an impact of the possibility of taking organs *post mortem*.

4) **Insist** on the bond that organ donation presupposes. Donation takes place in the framework of genuine social relationships. Those in charge of transplant coordination, whose number is insufficient in France, must follow up live donors for a considerable length of time after donation. The donation chain is a chain of bonds.

5) **Using a more precise vocabulary** could change the perception of reality. Instead of using the inexact expression "cadaveric donation", it would be preferable to speak of "*post mortem* organ harvesting". Nor does the economic wording "shortage" sit well with the ethical principles of the non commercial nature of the human body and of donation being free of charge.

6) **Exercise the utmost caution** in the event of an ethical debate concerning Maastricht category III: the eagerly awaited April 22, 2005 law, referred to as the Leonetti law, on the curtailment and discontinuation of treatment is not the equivalent of an authorisation to remove organs in such a situation. This law can only be freed of any suspicion as to its intentions if it is fully understood.

7) Reinforce the **trust of society as a whole** in the dialogue pursued with the hospital coordination teams who are responsible for harvesting organs. This dialogue requires extreme competence; it must never be experienced as an intrusion in the privacy of the deceased person's family. It must be seen **as moral support to the bereaved**, regardless of whether organs are, or are not, harvested.

Paris, April 7, 2011