

SPECIAL ARTICLE

LEGISLATION ON ORGAN DONATION THE FRENCH EXPERIENCE

M Broyer

INTRODUCTION

One of the most important aspects of kidney transplantation are the legal aspects. These are matters of decision for the people as a whole and should not be the decision of the doctors or even the Ministry of Health. The legal aspects of kidney removal in France could be divided into two periods. Before the end of 1976, there was no legal basis for kidney removal in France for transplantation purposes and it could have been theoretically possible to consider donation of a kidney by a living donor as a self-inflicted injury and to legally punish the volunteer donor and the surgeon. Similarly even sampling of the kidney from a cadaver was not really legal except with the consent of the family. As a result retrieval of kidneys was few and far between as many doctors were reluctant to ask for permission at the precise moment.

THE FRENCH LEGISLATION

It was precisely for these reasons that an eminent French nephrologist Professor J Hamburger and some of his colleagues and politicians decided to legalise the removal of organs for transplant purposes. They were guided by the publication of the International Society of Transplantation in 1970 which states "It is desirable to make use of all organs and tissues after death that would save life and lead to curing an individual in danger. But if the patient had stated during his life time his aversion to such a donation, this should be entirely respected."

A proposal along the above guide-lines was then introduced into the French Senate and the moral issues, philosophies and religious aspects were debated at length. In France as in all countries people are naturally attached to the corpse of a relative and would not tolerate a lack of respect towards it. It is pertinent to note that the Catholic Church, the Reformative Church, the authorities of Jewish and Islamic religions all accepted the principle of organ removal if it was to save another life. With this background both the Parliament and the Senate voted unanimously favouring the legal removal of organs for transplant purposes and this was made law in December 22nd 1976. The law consists essentially of 5 Articles.

**Hoptal des Enfants Malades — Necker
Paris, France**

M Broyer
Professor

**This paper was delivered at the recent
symposium on "Organ Donation —
Whose Responsibility" sponsored by
the National Kidney Foundation,
Singapore.**

Article I

This concerns the living donor and states that an organ to be used for transplantation or other therapeutic purposes in a human subject could be removed from a living donor who is of age and in full possession of his mental faculties. If the prospective donor is a minor, an organ may be removed only if he or she is a brother or a sister of the recipient. The consent of organ removal must be given by a legal guardian or representative and the procedure must in addition be authorized by a committee of at least three experts nominated by the Ministry of Health. A refusal on the part of the donor to donate an organ in all cases must be respected.

Article II

This is the most important in respect to cadaver transplantation. The article concerns cadaver donors and states that an organ to be used for therapeutic and scientific purpose may be removed from the cadaver if the person during his life time has not made known his refusal to such a procedure. However, if the cadaver is of a minor or a mentally defective person, organ removal must be authorized by his legal guardian or representative.

Article III

This states that organ removal as referred to in the preceding articles cannot be the object of any monetary gain. This does not exclude reimbursement of any contingent expenses incurred by the hospitals.

Article IV

This article states in detail how a living donor will be informed and refusal to cadaveric donation can be expressed. It also lays down the minimal criteria a hospital must satisfy before it could be authorized to carry out organ retrieval and the procedures and methods to be used in certification of death.

Article V

This concerns cornea grafts and the therapeutic use of human blood.

THE PUBLIC RESPONSE

Contrarily to expectations, there were few comments in the newspapers and the law was well received. When asked, the majority of people answered positively considering it was normal to remove an organ from a corpse if such a procedure could save a life. It was more difficult for the authorities to implement the law and a number of expert committees were formed to work out the details.

THE ADULT LIVING DONOR

The adult living donor of a kidney must be fully informed of all possible information of living with one kidney by the doctor responsible for the transplantation procedure. The doctor must deliver in writing a certificate to this effect. With this certificate the donor must have an interview with a judge at a local tribunal and a final certificate signed by the judge is to be deposited in the hospital files.

THE CADAVERIC DONOR

Refusal for removal of any organ at death is kept in a special register left at the disposal of anyone in the administrative office of a central hospital. The evidence of

refusal could be direct declaration of the person before his death, written document from the person or declaration from any individual who has proof to such an opposition from the person.

CERTIFICATION OF DEATH

Certification of death is delivered by two doctors not involved in the removal or transplantation procedure. Criteria of death as laid down by the French Academy of Medicine is recognised as valid by the Ministry of Health. The French government did not want at this time to legalise the definition of death but the criteria has been set out by the Ministry of Health in 1968 taking into account the scientific progress that has been made for defining brain death. In short it includes methodical analysis of the clinical history, absence of spontaneous respiration, muscular tone and brain stem reflexes. Sedation with drugs, alcoholic intoxication and hypothermia are specifically excluded. Sufficient period of time must elapse to ensure irreversibility. Hospitals authorized for the removal of organs must have adequate medical staff and technical means to make a diagnosis of brain death as laid out in the regulation.

RESULTS OF LEGISLATION

The results of legislation passed in 1976 are just being felt. Before 1976 the average number of transplantations carried out per year was about 400. In 1981 the figure has risen to 750. In the first 5 months of 1982 about 800 transplants have been carried out. This number still remains far below the needed number of transplantations in France. Nevertheless what is encouraging is the steady increase since the publication of the law and the impression that this law is more and more applied in hospitals throughout the country.

TRANSPLANTATION VERSUS DIALYSIS

With few exceptions, nephrologists favour transplantation to dialysis. There are two major reasons for this bias. The first is the totally different quality of life given by a successful transplantation versus haemo or peritoneal dialysis. This is particularly true for young people who could be totally rehabilitated. Dialysis is often difficult to stand, takes a lot of time and allows only transient biochemical improvement. Also symptoms of anaemia and general fatigue persist. After a successful transplantation such symptoms disappear, women could bear babies and children could grow normally. Hence for at least in young people with renal failure, kidney transplantation is the treatment of choice.

The second reason is economic. Dialysis especially hospital dialysis is extremely expensive. Dialysis is therefore a "closed" system limited by available funds and number of dialysis beds which could not be increased indefinitely. Transplantation on the other hand is an "open" system limited only by the number of available kidneys. This could be increased as more and more hospitals start to implement the Legislation.

CONCLUSION

As we are all aware, transplantation is a very complex matter. Legislation is an important point but not only the one to consider. An on-going education plan involving doctors, patients and the public through the mass media is most important.

Finally a reference to other countries in Europe may be pertinent. The Council of Europe on May 11th 1978 passed a resolution very much like the French legislation. Governments in Italy, Spain and most of the East European coun-

tries have enacted similar decrees. On the other hand countries in Northern Europe and the United States still require formal permission from the person during his lifetime or from a member of the family before the organ can be removed for transplant purposes. Therefore essentially two types of laws are available with regard to organ donation. The laws which involve the consent of the individual before death or the family (opting or contracting-in) generally applies in Northern Europe, and the United States, and the laws which does not implicate the consent but eventual refusal (opting or contracting-out) and which

were enacted in France and Southern Europe. It is stated that in the first group of countries where consent is needed, the people there are generally more civic-minded, better educated and less tradition-orientated. In the second group of countries, tradition and culture play an important part in the lives of the citizens and these are often in conflict with modern medical practice. Hence legislation of some form would be needed to increase the availability of cadaver organs to provide for the needs of patients who would otherwise die or spend the rest of their life on dialysis.

ATTENTION ALL ORTHOPAEDIC SPECIALISTS

In the field of **Orthopaedic dermatology**, trials on **Sebamed** have been conducted by

- i) Prof. Dr Rossak, Karlsbad
- ii) Prof. Dr. Schlegel, Essen
- iii) Dr Schwarzweller, Hamburg

The frequent diseases which demand active therapy from the orthopaedic specialists can be divided into the groups:-

- i) Intertrigenous eczemas
- ii) Hyperhidrosis
- iii) Microbial dermatosis
- iv) Various eczema
- v) Ulcus cruris with inflammation of the connective tissues and thrombophleboes
- vi) Skin alteration and eczemas caused by plaster casts
- vii) Allergies to dressings.
- viii) Inflammation of stump after amputation and ulcerations.
- ix) Petechiae after Zinc-Lime dressings.
- x) Allergies to medications and their efflorescences of the skin.

Sebamed with its remarkable ability to preserve the skins acidic mantle thereby exhibiting antifungal, antimycotic and antibacterial properties has been successfully employed to aid the above therapy. It gently decreases and can heal and relieve itching in allergic conditions.

Sebamed is extremely well-tolerated and no allergic side effects are reported at all.

seba Soap-free[®]
med



For further information, please contact:
Sebamed Information Bureau, Jardine Parrish Tel: 3371261

