INTRODUCTION

The legal and ethical aspects of human organ transplantation vary from country to country, although in broad terms the legal and ethical requirements denote substantial similarities. This chapter provides an overview principally of the statutory requirements relating to heart transplantation.

The major legal issues that pertain to human organ donation include:

1. Consent by donor or by those authorized by law to speak for the donor;
2. Legal tests and doctrines applied to organ donors;
3. Determination of time of death of donor;
4. Professional liability or medical malpractice;
5. Ethical and economic considerations.

INFORMED CONSENT

Competent adults

When dealing with adults of legal age and sound mind, their rights of self-determination and privacy rank supreme and are fundamental. When the transplant donor or donee is a competent adult, his or her consent should be given freely, knowingly and intelligently after being fully and reliably informed regarding the transplant procedure, its material risks, prognosis, and all alternative procedures. The doctor may not induce consent by minimizing the dangers of the surgery, or by misrepresentation or duress.

Donation by a competent adult prior to death

Any person may make such a donation to be implemented after his death: (1) in his will, if he is competent to make such a will; (2) in any document attested to by two competent witnesses; (3) by an oral statement made by the deceased during life in the presence of two persons of at least 18 years of age; and (4) by wearing a prescribed identity tag issued by an approved institution (e.g. driving license). Any such donation may be revoked prior to death by the donor.

In the USA the Uniform Anatomical Gift Act of 1968, and amended in 1987, allows any individual of sound mind who is over 18 years of age to make a gift during his life by will (to be effective immediately upon death without waiting for probate), or by a card or other document. If the donor is incapable of signing for any reason, including sickness, then the document can be signed on his behalf, if validated by two witnesses. The amended Uniform Anatomical Gift Act of 1987 added provisions for routine inquiry, required requests, presumed consent for Medical Examiner cases, and prohibition of the sale of human organs.

The system of donor cards has the merit of simplicity and portability. A typical example is the Uniform Card developed in the USA following the Uniform Anatomical Gift Act. This card, which can be carried easily in a pocket or wallet, states in simple words the donor’s desire to make an anatomical gift to take effect upon death. On the reverse side the card contains provisions for signature, witnessing and personal details. Similar cards are available in several other countries, including Australia, Canada and Britain. In Britain, under the Human Tissues Act, 1961, a patient may carry a signed donor card or record his wishes 'in writing at any time or orally in the presence of two or more witnesses during his last illness'.

Donation by a relative of the deceased

In the absence of specification by the individual while alive (as above), permission to donate organs at death may be obtained from certain specified next of kin of the deceased, i.e. the adult or legally competent spouse, child, parent, brother or sister, provided the deceased donor had not forbidden such a donation. Prior to actual organ removal, any donation by a relative may be revoked by the next of kin who made it. In this context legal competency refers to a person of sound mind who is over the age of 18 or 21 years, depending on the legally specified age of majority for the country.

In the USA, relatives of a deceased may also legally donate by document, telegraph, recorded telephone or other recorded message; in order of legal priority the next of kin are the spouse,
adult children, parents and adult siblings. In many countries "relative" is not defined.

**Donation by an authority empowered to donate after death**

The acquisition of hearts in the absence of donation (as above) may be possible in some countries. If a relative authorized at law to consent to a donation cannot be traced, the law of some countries may allow for a designated official to authorize under certain prescriptions the removal of tissue from a deceased person for purposes of a donation, e.g. the District Surgeon in South Africa, and the Coroner in England and Wales. In the USA, however, the law makes no actual reference to the deposition in use of an unclaimed cadaver. A few states allow transplantation of certain organs (such as corneas) if a reasonable effort has been made to trace the relative; authorization must be given by the Medical Examiner.

An adult, mentally competent prisoner may be judicially compelled in the United States to submit to lifesaving treatment, including human organ transplantation, by a declaratory judgement and a temporary restraining order. The judge uses a balancing test weighing the patient’s non-absolute constitutional right of privacy and self-determination against the state government’s most significant interest – namely, the preservation of life.

**Minors and other incompetents**

When dealing with minors, mentally retarded patients, or psychiatric patients who are legally incompetent to give a valid consent, several legal problems can arise. As a general rule a court order will almost always be required before organ transplantation may occur. The consent of parents or guardians is also usually required. However, refusal by the parents or guardians of necessary treatment for the incompetent child or mental case may not always be conclusive. In those circumstances involving minors and incompetents the judge applies the doctrine of *parens patriae*, an equitable doctrine which, in essence, permits the juvenile court to act as a parent and attempts to protect the minor from the abuse or neglect by the real parent or guardians.

**Cadaver organs**

For cadaver donors, where an informed consent by the donor prior to death is unavailable, there are three considerations in obtaining the requisite consent. First, there must be a valid consent from one who is legally capable of granting such a consent (generally, next of kin). Second, the determination of the time of death should be in accordance with the law. Third, the removal of organs from one who has died from a violent cause involves the Medical Examiner, who has jurisdiction over the body. There are certain circumstances where the Medical Examiner may not approve organ donations, including homicide, poisoning, industrial accidents, car accidents involving other persons, and where there is a question of liability.

**Unclaimed bodies**

For unclaimed bodies, statutes generally require that one should wait 48 hours after the death of the patient, during which time the hospital that is in possession of the body must make a reasonable search for the next of kin. Until such a search is carried out, the body is technically not claimed. In addition, the physician who wishes to use the unclaimed body in a transplant procedure is required to obtain clearance from the Medical Examiner. The physician must document carefully all aspects of the transplant procedure in the medical records in an attempt to avoid future liability.

**Anencephalic**

Anencephalic infants represent an important potential source of organs. Organs from such infants could meet the bulk of the current demand for infant organs. Organs from stillborns and infants dying from other diseases are not generally suitable for procurement and transplantation.

The first transplant of the heart from an anencephalic infant in the USA occurred in October 1987 at the Loma Linda University Medical Center in California without legal incident. Subsequently, other parents requested that their anencephalic children be used as donors to help other children. It is noteworthy that the anencephalic does not fall under the category of brain-dead. Hence, the brain death statutes are inapplicable under those circumstances. However, in some states an anencephalic infant may fall under the category of either a patient in a ‘vegetative state’ or the ‘terminally ill’, or both, as defined by statutes. Without specific federal or state statutes that prohibit anencephalics from donating organs before actual death has occurred, it is conceivable that a State Court may order the organ donation of an anencephalic infant when death is ‘imminent’, in a matter of hours or days, if the parents, doctors, hospital, clergy, and a court-appointed guardian *ad litem* all approve of the donation.

**LEGAL TESTS AND DOCTRINES IN THE UNITED STATES**

**Simple judicial approval of parental consent**

In cases involving intra-familial transplants among minors and incompetents (e.g. mentally retarded and schizophrenics), where both parents agree, judicial approval has generally been granted.

In a 1972 Connecticut case, *Hart v. Brown*, the court approved a transplant between two identical 7-year-old twins, considered the medical ramifications, and stated that the parents’ motivation and reasoning had met with approval of the guardians *ad litem*, physicians, clergymen, and the court itself.

**Best interest test**

By statute in Louisiana, medical intervention must be in the ‘best interest’ of minors and incompetents. A 1975 Louisiana case, *In re Richardson*, involved a husband who brought an action against his wife to compel her to consent to surgical removal and transplantation of one of her minor’s kidneys for donation to the boy’s older sister. Such surgical intervention would invade the minor’s right to be free in his person from bodily intrusion, and was not shown to be in the best interest of the minor. In a concurring opinion, a judge stated that before the court might exercise