

Socio-Medico, Legal Aspects of Organ Transplantation

*Sadhana Kala**

And Lord Shiva was enraged and beheaded Ganesha. And Parvati was pained beyond grief. "Ganesha ! Oh my Son! My Son! Be it that it were me, " she wailed. And Lord Shiva was moved and transplanted an elephant's head onto Ganesha and Ganesha became the Deity of Learning and Wisdom.

Hindu Mythology

Introduction

TO THE multitude facing death through organ failure, the organ substitution technology has come as a true gift of life. But the new technology has raised in its wake, as indeed does every new advance in technology, a number of questions to which there are no easy answers. Moreover, these questions relate more to ethics morality and social norms rather than to the medical aspects of the new technology. As Ogburn (1922) has pointed out, new inventions and discoveries give rise to social and moral problems because social organisations and public norms and attitudes, change at a pace much slower than that required by the new technology. And this gives rise to social and cultural maladjustments.

As a major technology organ transplantation may solve important health problems, but it has created unanticipated adjustment problems for the government, the general public, medical organisation and the patient

and his family. New situations have risen, both within the medical world and in the larger society, for which not clear norms or rules exist. These are just about being formulated although organ transplantation has been a reality for nearly four decades.

New medical technologies and therapies have become extremely expensive interventions which few individuals can afford and few hospitals can offer. Question has therefore arisen whether the society can afford to continue to develop such costly therapies. Cost have therefore become a very important factor in the decisions about the development and diffusion of new technologies like the organ transplantation.

This paper presents an overview of the medical aspects of organ transplantation; ethical and moral issues in the selection of organ donors and recipients; the cost of the new technology to the individual and to the society; and the laws regulating the transplantation practices.

Medical

Consequent to some pioneering work, in particular by Alexi Carrel which won him a nobel prize in 1912, surgical techniques for organ grafting became available in early.

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1900's. But because of problems of graft rejection, organ transplantation became a reality only half a century later.

The first successful kidney transplantation between identical twin donor-recipient pair was done in 1954 at Peter Birgham Hospital, Boston, Mass, USA, and was followed by a series of similar transplantations at the same hospital. With the development of immunosuppressive drugs, which help prevent organ rejection, the first successful kidney transplant between non-identical twins was done in 1959 and the recipient lived for over two decades. The other development was the use of *cadaver donors*, first with kidney transplantation in 1950, and later, even more dramatically, with heart transplantations in 1960's.

Continuous improvements in medical technology -- Surgical techniques, histocompatibility testing, typing reagents, crossmatching techniques, immunological conditioning with blood products, and most importantly, the development of immunosuppressive regimes -- have revolutionized organ transplantations and have made it a world wide practice. Kidney heart, liver, lung and pancreas transplantations are already being done, and transplantation of big intestine is foreseen in the near future. Moreover, the survival rate of transplant patients has increased dramatically: one-year patient survival rate for kidney transplant is 92-95% ; for heart 75-85% for liver, 65-70% and for heart-lung, 50%.

Notwithstanding these successes, organ transplant is not a panacea. Besides the risk of organ rejection or failure the patient is faced with recurrent infections and a life-time compliance with treatment regimes. Immunosuppressive drugs have several side affects and global immunosuppression rendering the patient vulnerable to infections. Several new drugs are now entering clinical trials and with these it will be possible to develop protocols tailored to in-

dividual patients and to specific situations. But problem of global immunosuppression and side effects remains. And although the dose of the drug may be tapered with time, a **withdrawl** is not possible because it almost inevitably leads to graft rejection.

The area where considerable research is needed is that of organ preservation. At present kidneys can be preserved for upto 48 hours, and even longer using a pulsatile perfusion apparatus. Liver and heart can only be stored in the cold. Liver preservation is limited to 8-10 hours and heart preservation is limited to 3-4 hours. There is a pressing need to extend the time of preservation so that the organs can be effectively distributed.

The need for organ preservation is all the more necessary because efforts to develop artificial organs have not succeeded. Despite an investment of nearly half a billion dollars and 30 years of research, a fully implantable and effective artificial heart is yet to be developed. Experimental transplantation of primate organs into human patients, done in 1960's was such a failure that it has been generally abandoned. The other objections to xenografting are severe shortage of primates, high costs, graft failures and moral objection on grounds of speciesism.

It is obvious therefore that human organs will continue to be the mainstay of organ transplantation therapy. The transplantation technology has made tremendous progress in the last decade. The 10-year survival rate with a complete rehabilitation now stands at 70%-80%. However the success of the therapy has brought forth problems and issues which were dormant when the technology was in the experimental stage. With the advance in the technology, patients who were earlier considered unsuitable for transplant, are now being included, and the number of patients awaiting organ transplant has been growing. The supply of organs on the other hand has not increased at the same rate and thus the gap between demand and supply has

steadily widened. Consequently, there has been considerable increase in the waiting period for the organs resulting in slow deterioration in the patient and thereby reduced chances of success of transplantation. In the US, for example, nearly 10% of the patients on the waiting list die for lack of organ supply, and only 60–70% of the waiting patients can be transplanted every year. Pressure has therefore been mounting to increase the supply of organs and to reduce the demand for them. This has accentuated the debate on socio-ethical and legal (public policy) issues connected with organ transplantation. Two major issues being organ donors and the selection of recipients.

Donors

Cadavers are the major source of kidney and the only source of other organs. Ninety six percent of the kidneys in Europe, 98% in Australia and 65% in the USA come from cadavers. The moral and legal constraint is that organs can be taken from a body only after the person is declared dead. Irreversible cessation of circulation and respiration is the traditional, time honoured, method of determining death. However, suitability of organs for transplantation diminishes rapidly once respiration and circulation stop. A new definition of death was therefore needed to ensure retrieval of suitable organs cadavers.

This was provided in 1968 by an adhoc committee of Harvard Medical School, Boston, which proposed “a new criteria of death” : total and irreversible loss of the functioning of whole brain. This concept of Brain Death has been recognised by many countries. But some countries, eg Japan, do not acknowledge it. Also some groups do not accept it on religious grounds and some doctors on medical grounds.

In a modification of the “brain death” definition, it is argued that many people believe that a person is dead when he loses the higher brain functions of consciousness

and cognition, rather than the brain stem’s integrative capacity. It is argued therefore that once the higher brain is dead -- that is, a person loses the ability to think, feel, reason, plan and so on -- the person is dead. This definition has not received much support at present. However as the demand for the organs increases, the pressures to accept the “higher brain death” definition will mount, and it is more than likely that in the next decade or two it will become an acceptable definition of death.

Since brain death is difficult to diagnose in infants and children, pressure is now mounting to either modify the definition of death, or to change the laws, so that organs can be retrieved from anencephalic infants, and in other pediatric situations of near death, to meet the growing shortage of pediatric-organ.

Acceptance of brain death has removed the moral and legal impediments to the harvesting of organs from cadaver. Mechanical devices keep the organs functioning while the brain is dead. The organs are thus retrieved in a condition suitable for transplantation.

But one of the difficulties being faced is that only 15% of the possible cadaver donors fulfill the role. Several new concepts have therefore been formulated to increase organ donation. US and UK have come out with “Donor Card” system where a person gives “explicit consent” for donation of organs on death. In this system, also known as “opting in”/“contracting in” system an appropriate family member can also give the required approval. In the other system, the “opting out”/“contracting out” (“presumed consent”) system, it is presumed that the organs may be removed for transplantation unless the deceased was known to have objections to the use of his organs for transplantation. The “presumed consent” method is in use in several European countries such as Australia, Greece, Spain, Sweden and France.

Another way to increase organ availability is to give financial incentives to organ donors. This could be either in cash or in kind. In the US a bill was introduced in the congress to give a twenty five thousand dollar deduction in income tax per qualified organ donation in the last taxable year of donor's life. The bill was not passed. The arguments for paid donations are that it will give poor a chance to break out of poverty cycle; will motivate people to donate organs on death since their estates will benefit; will prevent organs black market ; and that in the present system everyone except the donor benefits: the recipient gets a healthier organ, the transplantation team gets financial remuneration, but the donor gets nothing. It is also argued that on the concepts of liberty and privacy, the society has no right to intervene if a competent, autonomous, adult, decides of his own free will, to donate an organ in return for some incentive. Notwithstanding all the above arguments, commerce in organs is morally reprehensible all over the world. Such commerce will have a strong negative impact on the society, the medical profession and the transplantation programme. On the other hand, if sufficient cadaver organs cannot be made available, then the pressure for paid organ-donation will build up. Under such a situation it is possible that the society may accept organs market as an inevitable evil.

Recipients

It is obvious that in the foreseeable future the organ supply will continue to be much less than the demand. It will therefore not be possible to give transplantation to all the patients on the waiting list. A selection will have to be made. But it is not easy to decide who should get transplantation and who should not. The selection criteria have to meet the demands of medical suitability, ethical and moral acceptability, equity fairness and justice, and cost effectiveness. In addition, to be credible, these criteria have to

be open, and available for public scrutiny and debate.

Several approaches have been suggested to resolve the ethical problems in organ allocation. Basically these approaches attempt to construct an ethical structure based on concepts such as rationing distributive justice and value based system, and derive from these the distributive principles and finally the set of principles that will *maximise* the outcome. These concepts are then applied to the basic medical consideration to decide upon organ allocation. The suggested ethical models are :

- The medical model which *maximizes* life years.
- The economic model aims to minimize cost per life year saved.

The economic and social model seeks the maximum rehabilitation potential.

Some of the basic medical considerations to which the abovementioned ethical concepts have to be applied are :

- Age. How should utilizing transplantable organs in patients with 5 or 10 years life expectancies be weighted vs. utilizing them in those with 40 years or 50 years of functional potential ?
- Potentially Recurrent Diseases. Whether patients with diseases which reduce the long term success rate of transplants be ranked differently from those with "curable" conditions.
- Retransplantation. the graft loss rate is increased when a prior graft was lost. Whether there should be a limit on the number of organs that will be utilised in a recipient who has experienced repeated graft losses.

- **Noncompliant Behaviour Pattern.** This is the most common or at least a very common cause of transplant loss after the first year. Whether patients who have behaved in a non compliant fashion, particularly patients who have lost a prior transplant because of compliance failure should be considered because of compliance failure should be considered for transplantation? And, if so, what proof of compliance should be required of them in order to put them on a recipient list with no negative weights?
- **Waiting Time.** Excluding true medical urgency, how much weight should be given to waiting time? Suggestions have been made extending from making this the major criterion to totally ignoring it. Clearly among those equally qualified to receive an organ, waiting time is a fair criterion for allocation. The question becomes difficult when it has to be weighed in relation to other criteria.

On a practical plane we are still left with the problem of how the scarce organs are to be allotted. Halasz has suggested that some proportion (50% or more) should be given to low risk individuals with long life expectancies, in whom minimum of complicating factors exist, and who therefore can be expected to have the greatest long-term benefit from transplantation; another proportion (perhaps 25%) could go to high risk recipients; including those with an urgent need; the remainder could be allocated to those not covered by these categories. The US formula for organ allocation assigns sixty-six percent weightage to medical benefits. Starze formula gives eighty percent weightage to equity. Veatch has proposed fifty-fifty compromise between efficiency and equity. It can be seen that despite a well argued

ethical structure, the practical formula for allocation of organs is difficult to work out.

Cost

It is clear from the preceding discussion that even on purely medico-ethical considerations it is a difficult task to determine who should have access to life prolonging procedure like transplantation. Once the cost factors are built-in, the task becomes even more difficult and complex.

Costs are, nevertheless, too important a factor to be left out. A society has finite resources and therefore cannot go all that is conceivably possible. The scarce resources have to be carefully used to produce the maximum benefit for the society. Health care is not the only good in life, and resources have to be used to get other goods also. Even within the health care sector, resources have to be distributed among various therapeutic procedure so as to produce maximum benefit for the society. Transplantation is a costly technology benefiting a relatively small number of people, at a very high cost to the society. How much the society should invest in such technologies, will therefore always generate a lively debate.

Determining transplantation costs is a highly complex task. To take an example, heart transplantation costs have been very widely studied and analysed in the US. But even for these, there is a wide disparity between various cost estimates. The cost estimate for a heart transplantation patient, alive at the end of one year, vary from a low of eighty thousand dollars to a high of two hundred thousand dollars! Cost estimates for every additional year of survival vary from 10-20,000 dollars a year, and cost of life-year saved (*ie*, total cost of transplantation divided by the number of year the patient lives) varies from 23-35,340 dollars a year. Cost estimation of 'quality of life' is even more controversial. Similar disparities exist in the cost estimates of other transplantations.

Even more important than the cost of individual procedures is the total cost to the country. To calculate the cost to the country we need an estimation of the total number of transplantation procedures that would be needed every year. In the US, it is estimated that 60 per million of population would need transplantation and on application of medical criteria, 9 per million would be acceptable. If we use the US figures to make a very rough guess about the transplantation requirements in our country, the number of people needing and suitable for transplantation would be nearly 8,000 a year; and the expenditure would be 664 million to 1.4 billion dollar (Rs. 2,324 crores to 4,900 crores) a year. The total allocation for Health and Family Welfare in the eighth plan is Rs. 8,300 crores ie about Rs. 1,660 crores a year. It is obvious that only a very small fraction of the people needing transplantation can actually be given one because of the country's resource limitations. One point about the cost-to-the-country guess-estimates given here. If these appear to be too speculative then these should be compared with similar estimates made in the US. Estimates for cost of heart transplants in the US vary from 200 million dollars to 4.500 million dollars a year!

Legal

Major problems in organ transplantation are not legal and thus neither are their solutions. Nevertheless, laws are needed to regulate the transplantation practice and to ensure that these follow the precepts morally, ethically and culturally acceptable to the society. In other words, these practices must be in consonance with the societal norms, although as brought out earlier, these norms themselves have to change to ensure optimal exploitation of the advanced technologies like organ transplantation.

As is to be expected definitive laws have been formulated in countries where organ transplantation has been an established practice for the past few decades : US, UK and

many European countries. In addition, since 1970, efforts have been made to arrive at internationally acceptable guiding Principles. WHO conducted a detailed study (1987-91) and proposed nine such Guiding Principles. In India, the first effort in this direction was made by Maharashtra which appointed a special committee to examine commercial transactions in human organs. The committee submitted a report which was to be enacted as a law in the state by the end of 1990. However, later it was decided to introduce a comprehensive bill on the subject in the Indian Parliament. Accordingly The Transplantation of Human Organs Bill, 1993, (Bill No XIX-C of 1992) was passed by the Rajya Sabha on 05 May 1992 and is now awaiting approval of the Lok Sabha.

In the US, Public Law 98-507, National Organ Transplant Act, was enacted on 19 October 1984 by the 98th Congress. In addition, the US also has the Uniform Anatomical Gift Act and the Uniform Determination of Death Act. It should be pointed out that in the US system these acts have to be adopted by a state to become a law in that states. while some of the laws (e.g. Uniform Anatomical Gift Act) have been adopted by all the states, and could therefore be termed as national laws, some other acts have not been adopted by many states and are therefore not national laws. For example, brain death (Uniform Determination of death Act) is not accepted by many states.

The UK has a comprehensive Human Organs Transplant Act, 1989. However of vital importance and great practical use is the booklet "The Removal of Cadaveric Organs for Transplantation—A Code of Practice Including Diagnosis of Brain Death," published by the Department of Health in October 1979 (revised edition in 1983). This booklet covers all the practical aspects of the subject including the criteria for diagnosing brain death.

The nine guiding principles proposed by WHO are in some way or the other reflected

in the laws of 41 countries, around the world. However, many countries -- for example Germany, Netherlands, Ireland, Israel, Switzerland, Egypt, Saudi Arabia and so on -- do not yet have any laws on organ transplantation.

The bill on Human Organs Transplantation pending in the Indian Parliament (Lok Sabha) incorporates the concepts of the WHO's nine guiding principles as well as some concepts from the US and UK legislation. However the Act has several ambiguities and omissions. It is expected that these will be resolved once the detailed under the Act are framed. In particular, the following points are worth considering :

- There should be an absolute prohibition on the removal of organs from the body of a living minor for the purposes of transplantation. This is to guard against a situation of conflict of interest when the parent or the legal guardian is responsible for the welfare of an intended recipient.
- The doctors and health professionals should be prohibited from organ transplantation procedure if they have reason to believe that the organs concerned have been subject of commercial transaction. This provision will restrict the commerce in organs.
- The fees to be charged by a person or a facility for organ transplantation should be justifiable in terms of services rendered. In case of doubt, the opinion of licensing or disciplinary authority should be sought before the fee is proposed or levied.
- Organs should be made available to the patients on the basis of distributive justice equity and medical

need and not on the basis of financial or other considerations.

It is impossible for public policy, or law, to keep pace with the rapid advances in the medical technology. It is therefore incumbent upon the professional bodies like the Indian Medical Association and the Medical Council of India to come forward with codes and protocols to meet the challenges of new technologies. We can take the lead from the American Medical Association (AMA) of the US and the General Medical Council (GMC) of UK. Both of these bodies have been at the centre of all debates about new developments and have greatly contributed to, and influenced, the formulation of public policy. In our country, where the public's and politician's knowledge of medical matters is scanty at best, it is all the more necessary for the professionals bodies to deeply involve themselves in public awareness and educational programmes, and in the public policy formulation debates. For example, the developments in the foetal cell transplantation will give rise to several ethical and legal problems. It is to be seen whether our doctors and professionals bodies will participate in the ensuing debates, or whether they will leave decisions in this important medical field entirely in the hands of ethicist, lawyers and politicians.

Conclusion

Rapid advances in technology cause cultural maladjustments because the societal norms, attitudes and public policies change much too slowly to keep pace with such advances. The dramatic advances in organ transplantation technology over the past decade have accentuated medical, ethical, moral, financial and legal dilemmas being faced by the society.

Development of immunosuppressive drugs combined with advances in medical technology, has revolutionized organ transplantation and made it a world wide

practice. However; immunosuppressive drugs have several side effects and also render the patient vulnerable to infections. Despite Considerable research, these shortcomings of the drugs have not been overcome yet.

Cadavers will continue to be the major source of organs. Although acceptance of "brain death" has improved the availability of organs, the shortages continue. To further improve the organ availability, concept of "higher brain death" has been proposed, but has not been accepted as yet. Similarly, there is considerable pressure to either modify the definition of death, or to legally permit retrieval of organs from anencephalic infants and from other pediatric situations of near death, to improve the pediatric-organ supply. Paid organ donation has also been suggested to increase organ supply and to prevent organs black market. Considerable research is also needed to increase the preservation time of organs, at present only a few hours so that these can be effectively distributed.

Several criteria have been worked out to select patients for transplantation. These criteria attempt to balance the ethical and medical considerations, while giving weightage to waiting time. Selection of organ recipients, nevertheless, remains a vexing problem.

Transplantation is an extremely expen-

sive intervention. The cost to society is so high that question have been raised about its utility to the society and the desirability of its development and diffusion. The poorer countries, in particular, will find it beyond their means to adopt the technology.

Legal issues in transplantation have started receiving attention only during the last decade. Countries like the US and UK, where transplantation has been a fact of life for several decade, have passed comprehensive legislations on the subject. WHO has also come out with a set of nine Guide Lines in 1991. Many countries of the world have adopted WHO guidelines in one form or the other. In India a Bill on organ transplantation is awaiting approval of the Lok Sabha (Lower House of Parliament). This Bill incorporates most of the concepts from WHO guidelines and from US and UK laws. By and large commerce in organs, and advertising for organs, is morally reprehensible and illegal in a large number of countries in the world.

In India professional bodies like the Indian Medical Association and The Medical Council of India have not played the significant role that they should in the formulation of public policy on new medical technologies. It is an imperative duty of these bodies, and of individual doctors, to lead the way in the formulation of such policies. ■ ■