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OBJECTIVES

HYPOTHESES

RESEARCH METHODOLOGY

RESULTS & DISCUSSION

FINDINGS

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MULTIPLE FACETS OF ORGAN TRANSPLANTATION IN A TERTIARY CARE HOSPITAL MANAGEMENT, INDIA

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ABSTRACT

First successful kidney transplantation occurred in 1954 & Liver transplant occurred in 1967, at U.S.A. Organs for transplantation comes from either from live donor or brain dead person. The major donor organs and tissues harvested from brain dead are heart, lungs, liver, pancreas, kidneys, eyes, heart valves, skin, bones, bone marrow, connective tissues, middle ear and blood vessels. Developed countries have pursued organ transplantation in a proactive manner as this is the only hope for end stage diseases. Allocation of donated organs of a brain dead person goes to their own citizens as the organ availability is scarce. Hence each nation has to promote the organ allocation fairly through transplantation committees and also has to provide the legal platform. The introduction of Act Transplantation of Human Organ facilitated the Indian perspective of organ transplantations. India has huge number of patients requiring organ transplantation, only handful of hospitals has infrastructure for transplantations. In western countries organs are transported to the patient site in contrast to India where patient is shifted to the place where organ is retrieved due to legal, transportation and infrastructure problems. The objective of this paper is to refine managerial plans and preparedness to have smooth operation of transplantation programme in a tertiary care hospital by look back of earlier efforts. Data of transplantation BGS Global Hospital, Bangalore, Media reports, Important Judgments in medico legal cases of transplantations has been used. Transplantation programmes in India are in upward phase. Problems faced are lack of organ donation awareness among public, patients and police, stringent laws and finance. Medical professionals working in transplantation field need to be facilitated legally, managerially and infrastructure wise to continue the highly skilled transplantation surgeries in India.

KEYWORDS

Organ Transplantations, Organ Allocation, Brain dead, Transplantation committee.

INTRODUCTION

First successful kidney transplantation occurred in 1954 & Liver transplant occurred in 1967, at U.S.A. Organs for transplantation comes from either from live donor or brain dead person. The major donor organs and tissues harvested from brain dead are heart, lungs, liver, pancreas, kidneys, eyes, heart valves, skin, bones, bone marrow, connective tissues, middle ear and blood vessels. Developed countries have pursued organ transplantation in a proactive manner as this is the only hope for end stage diseases. Allocation of donated organs of a brain dead person goes to their own citizens as the organ availability is scarce. Hence each nation has to promote the organ allocation fairly through transplantation committees and also has to provide the legal platform. The introduction of Act Transplantation of Human Organ facilitated the Indian perspective of organ transplantations. India has huge number of patients requiring organ transplantation, only handful of hospitals has infrastructure for transplantations. In western countries organs are transported to the patient site in contrast to India where patient is shifted to the place where organ is retrieved due to legal, transportation and infrastructure problems. Patients with end stage disease can be provided a new lease of life through cadaveric transplant programs.

The Transplantation of Human Organ Act, Act No. 42 of 1994, heralded a new era in Indian Surgery. This legislation was constituted on similar basis of UK Transplant Act. The Transplantation Of Human Organs Rules, 1995 defines Authority for removal of human organ, Duties of the Medical Practitioner, Authorisation committee, Preservation of organs, Composition of Authorization Committees, Registration of hospital and Conditions for grant of certificate of registration. The essence of this legislation is three folds: To accept the concept of brain death, to discourage commercial dealing in organs and also defined the first relative (father, mother, brother, sister, son, daughter and wife) who could donate organs without permission from the government. Organ transplant law does not permit exchange of money between the organ donor and the recipient. As per the Act, the unrelated donor has to file an affidavit in the court of a magistrate stating that the organ is being donated altruistically without monetary benefits. Live donor has to undergo number of tests before the actual transplant. In transplants where donor not a first relative, an approval had to be obtained by a government appointed authorization committee. The Authorization Committee for organ transplantation set up for the purpose goes through all the documents required under the act. If it is suspicious of money exchange in the process, both the recipient as well as the donor are considered as offenders under the law, as Indian law bans organ sales. Also no foreigner can get a local donor from India and the penalty for the organ trade is also very high. Every State has a Zonal Coordination Committee (ZTCC) for authorization of transplantation and are meant to scrutinize all applications for unrelated transplants, Organ sharing and to monitor their functioning of transplantation units. All hospitals conducting transplants have to register with ZTCC committees. Voluntary organizations and media have played a vital role in India on ethical issues to avoid malpractice in organ transplantation. State medical councils have powers of investigation.

As per the Transplantation of Human Organs Rules, 1995 (Gsr No. 51(E), Dt. 4-2-1995) as amended Vide GSR 571 (E), Dt. 31-7-2008, Form 1(A) need to be completed by the prospective related donor. The Report Of Transplant Of Human Organs Act Review Committee (as per the Delhi High Court Judgement dated 06.09.2004 in W.P. no.813/2004 to review the provisions of the Transplantation of Human Organs Act, 1994 and the Transplantation of Human Organs Rules, 1995) provided recommendations for where all proposed donors including 'near relatives' should be scrutinized by a committee (the authorization committee). Also defines composition of hospital based authorization committees, composition of state/ district level authorization committees, quorum of the committee, frequency of meetings, jurisdiction and guidelines for working of the authorization committee. These changes in law s are projected to make easy for genuine cases of transplantations to save life and at the same time increases the transparency in transplantation procedures and also to puts restraint for violation of the law.

In case of Brain dead patients, relatives are educated about organ donation by doctors and social workers. Multiple organs such as kidneys, liver, pancreas heart, lungs and corneas can be donated which saves several patients and rightly quoted as let some ones sunset can become sun rise for several. All religions on earth promote goodness and donation till our end. Hence organ donation is not having prohibition in any of the religion.

The ABO and HLA systems are major transplantation antigens in man. ABO antigens are present in most body tissues as well as on RBCs. Hence the organ transplanted has to be ABO group compatible with patient. Histocompatibility (HLA) testing is also performed in preparation for organ transplantation. Histocompatibility testing minimizes graft foreignness and reduce rejection of transplanted organ. The type of histocompatibility testing performed varies on the organ or tissue transplanted. The reasons for this variability are related to immunogenicity of organs and the cold ischemic times for different organs. It is advantageous to perform extensive histocompatibility testing for the most immunogenic organs. Patients can have HLA antibody as a result of transfusions, prior transplants, and/or pregnancies. Because the development of antibodies change over time, the potential renal transplant candidate is usually screened on a regular basis. Renal transplantations can be made safer by performing these tests. People who are transplanted cadaver kidneys, about 93% are still alive after 1 year, and 75% are alive after 5 years. However, the length of cold ischemia time an organ will tolerate limits the extensive testing. The maximum cold ischemia time for heart transplantation is 4 hours, restricts HLA typing between donor and recipient. Donor-specific cross-matching has limited relevance to liver transplantation because the liver allograft is relatively resistant to rejection. Liver is the least immunogenic without extensive tests transplantations can be carried. A shared organ between different hospitals increases the chance of equal distribution and increases the success rate of transplantations.

MOHAN Foundation of India started in 1997 in Chennai by philanthropists and medical professionals led by Dr. Sunil Shroff are committed to increasing the Transplantations of Human Organs to needy patients are doing a commendable job. The meaning of MOHAN Foundation is Multi Organ Harvesting Aid Network and is a support group for patient, physicians and public. They conduct awareness programmes for public, training programmes for counselors, donor memoirs, patient support group and Indian Network for Organ Sharing (INOS) along with a news letter on transplantation.

REVIEW OF LITERATURE

Transplantation medicine is one of the most challenging and complex technology of modern medicine. Main problem for medical management after transplantation is transplant rejection, can be reduced through HLA serotyping and use of immunosuppressant. A transplantation surgery encompasses distinct legal, ethical, financial, administrative and managerial issues apart from cutting edge technology.

LANDMARKS IN ORGAN TRANSPLANTATION ARE

- 1905: First successful cornea transplant by Eduard Zirm [Czech Republic]
- 1954: First successful kidney transplant by J. Hartwell Harrison and Joseph Murray (Boston, U.S.A.)
- 1966: First successful pancreas transplant by Richard Lillehei and William Kelly (Minnesota, U.S.A.)
- 1967: First successful liver transplant by Thomas Starzl (Denver, U.S.A.)
- 1967: First successful heart transplant by Christian Barnard (Cape Town, South Africa)
- 1981: First successful heart/lung transplant by Bruce Reitz (Stanford, U.S.A.)
- 1984: First successful double organ transplant by Thomas Starzl and Henry T. Bahnson (Pittsburgh, U.S.A.)
- 1997: First successful allogeneic vascularized transplantation of a fresh and perfused human knee joint by Gunther O. Hofmann
- 1998: First successful live-donor partial pancreas transplant by David Sutherland (Minnesota, U.S.A.)
- 2008: First baby born from transplanted ovary by James Randerson

Both developing and developed countries have promoted policies to increase the safety of transplantation and availability of organs to their people. Brazil, France, Italy, Poland and Spain have legality that all adults are potential donors with the "opting out" policy. In spite of changes in law, Potential recipients all over world are in misery due to long waiting list as a result of limited availability of donors. Limited availability of organs in the world is due to lack of awareness, lack of infrastructure, lack of emergency preparedness, lack of finance and managerial policies & process management.

The American Organ Transplant Association provides a comprehensive list of information of more than 60 Transplant Centers throughout the U.S. and several international centers along with access to complete list of an estimated 300 U.S. Transplant Centers linked to UNOS. Many countries have also put in place "opt-out" organ donation systems, known as "presumed consent" systems. Donation of organs and tissues can save lives when there is no hope available. Each day about 50-60 people receive an organ transplant while another 15 or so on the waiting list reach fatality because not enough organs are available. Typically a hospital representative will ask the family of the deceased (brain dead) to donate their organs and will proceed based on what the family wishes, regardless of the wishes of the person who is brain dead. United Network for Organ Sharing (UNOS) of USA is a private, non-profit organization that manages the nation's organ transplant system under contract with the federal government and are involved in many aspects of the organ transplantation and donation process, maintain the national transplant waiting list, matching donors to recipients 24 hours a day throughout year, Maintain the database that contains all organ transplant data for every transplant event that occurs in the U.S, develop policies that make the best use of the limited supply of organs and give all patients a fair chance at receiving the organs, They also provide assistance to patients, family members and friends, educate transplant professionals and public about the organ donation. Waiting list of patients waiting for transplantation goes up to lakh in USA and transplants in month of Jan. 2012 were 2236. Maximum numbers of transplants are done in USA.

In the UK only approximately 900 individuals become organ donors each year, while more than 6000 people are waiting for organs. 1000 patients each year die waiting as there are not enough organs available. National Health system, UK government organization promotes transplantation. 7,553 people were waiting for transplants on April. 2012. In UK from April 2010 - March 2011: 3,740 organ transplants were carried utilizing 2,055 donors organs. 1,008 lives were saved in the UK through a heart, lung, liver or combined heart/lungs, liver/kidney, liver/pancreas or heart/kidney transplants. Also 2,732 patients were significantly improved by a kidney or pancreas transplant. 156 patients received a combined kidney/pancreas transplant. 1,045 living donor kidney transplants were performed accounted for more than a third of all renal transplants. 'Non-directed' living donor transplants (also known as altruistic donor transplants) and paired and pooled donations contributed more than 60 kidney transplants. Almost 675,000 more people in UK pledged to help others after their death by registering their wishes on the NHS Organ Donor Register, bringing the total to 17,751,795 on March 2011.

The Australian Organ Donor Register (the Donor Register) is authorized by a service arrangement under subsection 7(2) of the *Medicare Australia Act 1973*. The Australian Organ Donor Register was established in November 2000 and is the only national register for organ donation for transplantation. The Donor Register keeps a record of donation decision and of the organ and tissue agreed to donate. Around 1700 patients in Australian organ transplant programme are in waiting lists at any time. Since 1965, more than 30 000 Australians have received transplants. Organ transplants are undertaken in both government and private hospitals in the South Africa. In the early days, the majority of transplants were carried out in government hospitals. Most are now carried out in private hospitals. However, a significant number are still carried out in government hospitals.

Countries that practiced the increases in organ donation during recent years are Spain and Italy, employed more transplant coordinators, started community awareness campaigns, installed 24-hour organ retrieval teams at their hospitals and enhanced training for doctors who counsel grieving families with brain dead patients. Spain, which has very high organ donation rates per lakh population, is best-known example.

Singapore implemented Medical (Therapy, Education and Research) Act (MTERA) in 1973 with Opt-in system allowed person to donate his body to therapy (including transplant), education or research and act also allows relatives to provide consent for donation. Later Human Organ Transplant Act implemented in 1987 with Opt-out system. HOTA (Human Organ Transplant Act) refers to the law that covers the removal of any organ from the body of a dead person to transplant to patients. Due to the amendments to HOTA the number of patients awaiting a kidney transplant dropped from 673 in 2003 to 605 in mid-2006. In 2004 -2006, at least 130 people have received transplants under the revised Act. Despite the opt-out kidney transplant law, which allows organs to be taken from accident victims, the waiting list grows yearly, with more than 660 on the list at the end of 2009. The average waiting time in Singapore is seven years for a cadaveric kidney. The first cadaveric kidney transplant in Singapore was performed in 1970 and first heart and liver transplants in Singapore in 1990. The increase in the number of organ transplant programmes in Singapore led to the establishment of the Ministry of Health National Organ Transplant Unit to facilitate organ harvesting to meet the requirements of the various transplant teams.

Sweden, which has an "opt-out" system, has a relatively low rate of donation in comparison with other developed countries and the United States has one of the highest rates. as Kieran Healy, a sociologist at Duke University explains this is not because of "opt-out" and "opt-in" systems in practice. In both, doctors still typically follow the wishes of the deceased's family, whatever the official donor status of the deceased. Organizational strategies in terms of logistics and process management are deciding factors in increasing organ transplantation therapy.

STATEMENT OF THE PROBLEM

Organ Transplantation in medical industry has helped in saving the lives of patients who would have died otherwise. There is immense requirement and want for human organs for transplantation. In fact, the need far exceeds the supply of transplantable organs. This disparity has led to the formulation of various legislations, attempting to regulate the scarce resources (human organs) and to establish an reasonably equitable system to allocate the organs where the most good is achieved. Worldwide, the demand for organs is growing every year, as the supply of organs and tissues for transplantation has not kept increasing with the demand.

Every year, almost two lakh people in India need kidney transplants and there are only 4,000 people donating them as per Narendra Saini, media co-coordinator of the Indian Medical Association in Delhi. Experts assess 15 % of adults in urban India are diabetic and 40 % of them are likely to develop kidney problems. Every Year over 1,50,000 new patients require dialysis or kidney transplant. We have lakhs of people suffering from liver, biliary and pancreas diseases in end stage requiring transplantation. The number of fatal road traffic accidents every year in India is constantly increasing and averages of about 8,500 per year. At any given time there are 8 - 10 brain dead patients in different hospital ICU's in several major cities of the country. Potentially a pool of brain death donors is available in India. One brain dead patient can help seven patients in critical stages to lead normal lives. No other fields of medicine have ethical, moral, legal, administrative and social issues as that of organ transplantation.

In 1967 the first successful cadaver kidney transplantation was done at KEM Hospital, Mumbai. In 1994 the first successful heart transplant was done at AIIMS, New Delhi and in 1995 the first successful multi-organ transplant was done at Apollo Hospital, Chennai. First successful cadaveric liver transplant in India done by Dr Soin in 1998. Countable number of hospitals has taken up transplantation programme. The Total Cadaver Transplants activities For various solid organs from Jan 1995 to Jun 2005 were - Kidney 379, Heart 34, Liver 12, Pancreas 02, Lungs 01 -TOTAL 428 were performed at 35 hospitals in the country from various regions have undertaken cadaver transplants. Chennai has done the maximum number of cadaver transplants in the country (189). Besides Chennai the other cities where the cadaver organ transplantation is taking place include New Delhi (68), Ahmedabad (46), Pune (32), Bangalore (32), Vellore (22), Mumbai (20) and Coimbatore (12). 13 hospitals in India from 1971 to Feb. 2006 performed total 12294 renal transplantations.

In India, there is a need of approximately 1,75,000 kidneys, 50,000 hearts and 50,000 livers for transplantation every year.* 5,000 kidney transplants in 180 centres, 400 livers in 25 centres and 10-15 hearts in very few centres are done annually.

A railway police from Mumbai refused to give an NOC to a hospital Feb.2012 to retrieve the organs of a deceased 61yrs male who was in a brain-dead state, collapsed at railway station and suffered an intracranial bleed. The GRP's contention was that the panchnama could only be conducted after the hospital issues a death certificate (complete death of a patient). After the standoff, deceased family withdrew its consent for the organ donation. Thus patients awaiting for transplantation and medical professionals specially transplantation team had a set back. Dr Pravin Shingare, the acting head of the Department of Medical Education and Research (DMER), said the government would soon issue a circular stating the protocol to be followed in case of brain-death donations. The circular will state that policemen should consider the brain-stem death certificate issued by hospitals as a death certificate. They should then carry out investigations and give the NOC needed by the hospital to retrieve organs. Each government- staff involved with accidents and postmortem need to be sensitized in a manner that the donor family's altruistic act is appreciated. In two recent medical negligence cases from Karnataka involving patient's undergone transplantations, showed irregularity in taking consent with one hospital lost the license to perform transplantation and another hospital has to pay the compensation. To promote brain death cadaver donation some changes are needed in Human Organ Transplantation Act like required intimation of brain death to relatives, procedures in law to make it obligatory for the ICU staff to propose organ donations and request their consent for the same. In accident cases with medico-legal status facilitated for 'post mortem' to undertake at the same time as the 'Organ retrieval' surgery procedures to be done simultaneously, Shifting patient from one hospital for Organ donation to another for post mortem makes relatives very emotionally traumatized and delays the process of handing over the body. Most importantly, there is a need to spread awareness at every level. Surprisingly, Nurses and Medical students also do not know about the Act. That means that they need to be educated more about the Act, along with the rest of the population. It has been seen that the willingness to donate organs is directly proportional to the level of education, which needs to be increased. We must take up organ transplantation programme to where it really is in the right places as a modern medical advance permitting one human being to make the gift of life to another. We should make organ transplants affordable by the average citizen in our public institutions and all suffering patients get a chance to live irrespective of caste, age, sex, strata and language.

IMPORTANCE OF THE STUDY

Organ Transplantation is a tertiary care treatment need to be offered to patients with organ failure as a only hope to live. Hence in this study we have explored the key issues of transplantation setbacks and success in different nations, license, prerequisites to set up transplantation centre of managerial concerns, introspect few judgments of transplantation related medico legal cases and promotion of organ transplantation through zonal centres and tertiary care hospitals towards betterment of Indian transplantation programme.

AIMS AND OBJECTIVES

To refine managerial plans and preparedness to have smooth operation of transplantation programme in a tertiary care hospital by look back of earlier efforts.

MATERIAL AND METHODS

Data of transplantation BGS Global Hospital, Bangalore, Media reports, Important Judgments in medico legal cases of transplantations.

RESULTS & DISCUSSION

The Zonal Coordination Committee of Karnataka (ZCCK) is situated in Bangalore. Purpose of the Zonal Coordination Committee of Karnataka to realize the cadaveric transplant program in the state of Karnataka with goal of increasing availability and access to donor organs for patients with end stage organ failure. They are supervising efficient cadaver organ procurement and also involved in fair distribution. A System of organ sharing is Set up has organ allocation criteria,

Provided a system that immunologically sensitized patients are offered best possible solutions, Minimize wastage of organs, assurance in quality control by collection, analysis & publications of data on organ transplantations, add to public awareness, make easy availability of organ donors by conducting awareness programs.

To facilitate availability and transplantation of organ for organ failed individuals, the procedures followed is given below:

Uphold a recipient waiting list of patients referred by hospital, patients will be registered at ZCK office, organs allocated as & when available as per the criteria(criteria will be revised from time to time in consultation with the medical fraternity), facilitate organ retrieval & transport, carry out public awareness programs. The purpose of the transplantation registry is to collect data for continuous evaluation of status of transplantation in the state of Karnataka. Every recognized transplant center should submit to ZCK following information every month including activities of the coordinator appointed by the hospital towards the promotion of the cadaveric programme, List cadaveric transplant promotional activities. Each recognized transplant center should have "Counseling Mechanism" within their hospitals to care for the needs of families of critically ill patients. Every center should have an ethics committee to attend to various ethical issues. To facilitate working of ZCK has Management committee members and Executive committee members.

Establishment of Transplantation centre:

Global Hospitals in India started transplantations because of visionary Dr.K.Ravindranathan realizing the significance of transplantations for Indian people and exceptional transplantation units started in Hyderabad, Chennai and Bangalore. Many more units in major cities are coming up phase wise.

1. License to perform Transplantation surgery- BGS Global Hospital is a tertiary care hospital with Neuro ICU, well equipped Transplantation OT and renal/cardiac/liver ICU facilities. Hospital has License to perform renal, liver, heart, lung and haemo transplantation.
2. Human resources-Hospital has team of transplantation surgeons trained abroad, trained OT/ICU/Ward staff, transplantation coordinators.
3. Infrastructure-BGS Global Hospital has provided infrastructure on par with best technology available in the world for transplantations.
4. Supportive services-Supportive services LIKE lab, radiology, bloodbank, physiotherapy and dietary care is available. Administrative and managerial services of the hospital fully support transplantation day and night. Legal formalities are completed with at most care.
5. Transplantation committee- Hospital has Transplantation committee to review cases and to increase the efficiency of transplantation services.
6. Intensive care for transplantation recipient and donor- Intensive care for transplantation recipient and donor is available.
7. Post transplantation Follow-up of patients are provided- Care of Post transplantation complications dealt by team of physicians and surgeons.
8. Review of transplantations is done by Transplantation committee and hospital management keeping in view continuous quality improvement.

We started transplantation programme in 2009 and our statistics are -

Year	KIDNEY TRASPLANTATION	LIVER TRASPLANTATION
2009	5	0
2010	7	6
2011	12	3
2012 upto 15.04.2012	9	5
Waiting list of patients on D.15.04.2012	59	21

	Total Transplantations	Live donors	Brain Dead Donors (Organ Allocation)
KIDNEY TRASPLANTATION	33	26	7 (4 organs own hospital & 3 organs other hospitals)
LIVER TRASPLANTATION	14	1	13 (8 organs own hospital & 5 organs other hospitals)

We have also geared up towards heart, lung, pancreas and bone marrow transplantations. Efforts made by our hospitals will contribute towards better transplantation programmes in India and in future each deserving patient will get an opportunity to survive.

CONCLUSION

Transplantation programmes in India are in upward phase. Problems faced are lack of organ donation awareness among public, patients and police, stringent laws and finance. Medical professionals working in transplantation field need to be facilitated legally, managerially and infrastructure wise to continue the highly skilled transplantation surgeries in India.

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