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Worldwide Cadaveric Organ Donation Systems (Transplant Organ Procurement)

KAZEMEYNI SM[1], BAGHERI CHIME AR[2], HEIDARY AR[3]*

[1]*Department of Urology, Dr. Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran*

[2]*Department of Neurology, Tesocoba University, Japan*

[3]*Management Center for Transplantation and Special Diseases, Ministry of Health and Medical Education, Tehran, Iran*

Introduction

Organ transplantation, thanks to scientific and technical advancements, is considered as a successful daily procedure. Over one million people worldwide have received allograft organs and some of them have already survived more than 25 years.(1) Five-year survival rates for most organ transplant programs are around 70%.(1)

Ever-increasing need to transplant organs has led to different approaches and methods in different countries in view point of transplant organ procurement. Each system in organ procurement for transplantation has peculiar advantages and differences in their functions and donation rate are due to structural and cultural differences.

The survey of all different systems in the world shows even the most successful ones can not provide all the needs to transplant organs; how ever, living donation in some organs like liver, kidney, and lung has grown by following scientific and ethical issues. There are currently nearly 40000 patients waiting for a kidney in Western Europe.(1) Mortality rates for patients waiting for a heart, liver, or lung range from 15% to 30%.(1)

The main purpose of this article is to briefly introduce different units/organizations in the world concerning transplant organ/tissue procurement. Considering a three-year activity in cadaveric organ procurement in Iran by the establishment of Iranian Network for Organ Procurement, comparing results and following useful experiences gained by leading countries in organ procurement can promote cadaveric organ donation to higher the current rate, 1 pmp (one per million population).

Corresponding author: Management Center for Transplantation and Special Diseases, Vanak, Tehran, Iran. email: omid1350ir@yahoo.com

Transplant Organ Procurement Unit/Organization/System

Common aspects of different organ procurement units in different countries are presence of a center for national coordination and centralized organ allocation, presence of independent organ procurement unit in each hospital with transplantation department, and management of making connection with nation wide hospitals without transplant programs.

There are also differences in multiple phases of organ procurement, which will be mentioned later. These differences are emerged from different approved protocols in different countries. One of the discriminative issues is family approach and getting consent.

Even though we can consider two ways of family approach and getting consent as presumed (opting out) and informed (opting in), there is another way that we call it theoritically presumed consent, but practically informed. In countries without legal limitation with presumed consent system, merely for ethical issues, coordinators approach the family to get consent for organ donation. Different types of required consent in different countries listed in table 1.(1) Studies have shown that organ donation in countries with presumed consent is almost 15% easier. Nevertheless, even with same legislations and same national organizations, there are still differences in countries (such as France, Italy, Spain) in refusal rate for donation.(2)

Despite this supposition that donation rate is higher in countries with presumed consent, this rate is higher in Spain and the United States (table 1).

Hence, it seems that the type of consent is less important than the function of the system, general awareness, and presence of trained personnel

TABLE 1. *Types of consents required in different countries*[1]

Presumed Consent	Finland, Portugal, Austria, Sweden, Czech Republic, Slovakia, Hungary, Poland
Informed Consent	United states, Latin America, United Kingdom, Ireland, Denmark, Netherlands, Germany
Theoritically Presumed Consent, but Practically Informed Consent	Spain, Italy, Greece, Belgium, Luxembourg, France
Both Informed and Family Consent	Japan
Informed or Family Consent	Iran

in such systems. In 1998, cadaveric donation rates were 15 pmp in Europe, 22 pmp in the United States and 31.5 pmp in Spain as the leading one.[1] Data related to donation and transplantation activities is shown in table 2.

Procurement Organizations

Well-established organ procurement systems in the world have organ exchange organizations with a specific name in each country. ONT (Organization National de Transplant) in Spain, UNOS (United Network for Organ Sharing) in the United States, SCOUT (Saudi Center for Organ Transplantation) in Saudi Arabia, and JOTNW (Japan Organ Transplant Network) are some examples of these kinds of organizations.[3,4,5]

Centralized management and organ sharing are common tasks of these organizations. Continuous coordination between organ procurement units and transplant departments, equitable organ allocation based on approved protocols, and making connection with organ procurement networks in other countries are necessities to established such organizations.

Now, these international connections lead to donate organs to completely matched patients and in most cases to the ones with life-threatening conditions.

Iranian System

In Iran, centralized management and organ allocation are conducted in Iranian Network for Organ Procurement that is set up in Management Center for Transplantation and Special Diseases, affiliated to Ministry of Health and Medical Education.

Patients' waiting list is continually updated in this center and in case of donation, organ sharing is done here following a general allocation policy: in priority order, locally, regionally, and nationally in non-urgent (elective) situations. Approved phases for donor detection and identification, brain death determination, and organ/tissue retrieval are shown in figure1.[6] Moreover, table 3 indicates briefly different phases of organ procurement.

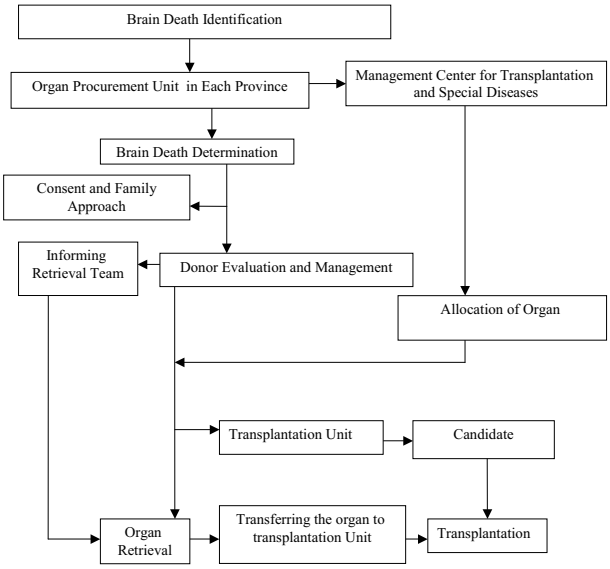

FIG. 1. Algorithmic approach for brain death detection, identification, referral, determination, and transplant organs retrieval in Iran

Designed systems for Iran is based on independent procurement units in each university of medical sciences. Some of these universities are working in this regard now and the others are going to establish such units.

Each unit has a chief transplant coordinator who is in charge of making connection with Iranian Network for Organ Procurement. Specialists who are in charge of Brain death determination, based on legislation and decree, should be appointed by the minister of health and medical education and none of them are members of any transplant teams.

In this system, two groups of coordinators have the major roles: transplant procurement coordinator (TPC) and recipient (clinical) coordinator. Organ allocation is managed in Iranian Network for Organ Procurement as a centralized conduction. Each university has its own waiting list and procured organs are implanted first locally, then regionally, and finally, nationally.

The United States' Model on Transplant Organ Procurement

In the United States, there is an organization that works independently from transplant centers or wards and consists of two sections: recipient section and Host Organ Procurement Organization, which practices under the supervi-

TABLE 2. *International Data on Organ Donation and Transplantation Activities in 1998*

Transplant Organization			E.T	E.F.G	H.T.S	HU.T	I.S.S.	O.N.T.	O.P.T.	P.T			SK.T	SW.T	UKTSSA	UNOS		
Countries Population × 10^6	Croatia 4.7	Czech Rep 10.3	113.4	France 60.02	Greece 10	Hungary 10.3	Italy 58	Spain 39.66	Portugal 9.96	Poland 38.64	Slovenia 2	Slovakia 5.36	23.99	Switz 7	UK+Ireland 62.71	USA 268	Canada 29.7	Australia 18.75
Cadaveric Donors P.M.P	22 4.7	198 19.2	1636 14.4	993 16.5	57 5.7	126 12.2	707 12.3	1250 31.5	166 16.7	289 7.5	27 13.5	83 15.5	358 14.9	108 15.4	846 13.5	5791 21.6	428 14.4	196 10.5
%Multi-organ Donors	0.5	57%	69%		68.4%	12.7%	79.1%	84.5%	78.3%	46.7%	85%	34%	65.6%	76.85%	53.2%			77%
Cadavedic Kidney Transplants P.M.P	41 8.7	359 34.9	2832 25.0	1815 30.2	87 8.7	233 22.6	1162 20.2	1976 49.8	305 30.6	534 13.8	46 23.0	145 27.1	650 27.1	193 27.6	1526 24.3	8939 33.4	676 22.8	358 19.1
Living Kidney Transplants P.M.P	13 2.8	7 0.7	523 4.6	73 1.2	82 8.2	8 0.8	79 1.4	19 0.5	5 0.5	9 0.2	1 0.5	3 0.6	242 10.1	68 9.7	241 3.8	4016 15.0	336 11.3	144 7.7
Liver Transplant(**) P.M.P	2 0.4	66 6.4	1071 9.4	693 11.5	18 1.8	19 1.8	549 9.5	899 22.7	134 13.5	27 0.7	4 2.0		193 8.0	77 11.0	690 11.0	4450 16.6	342 11.5	154 8.2
Heart Transplants P.M.P(*)	9 1.9	55 5.3	759 6.9	370 6.6	13 1.3	5 0.5	336 5.6	342 8.8	7 0.7	123 3.2	4 2.0	10 1.9	114 4.9	44 6.3	281 5.5	2340 8.9	154 5.2	72 4.1
Heart-Lung Transplants P.M.P			20 0.2	26 0.4			2	7 0.1					4 0.1		62 0.8	45 0.8		4 0.2
Transplants P.M.P(*)		8 0.8	228 2.2	36+52 1.9			65 1.2	26+95 3.2					57+22 3.5	3+27 4.3	48+36 2.3	849 3.3	75 2.5	34+49 4.6
Pancreas Transplants P.M.P		21 2.0	258 2.2	47 0.8		2 0.2	52 0.9	28 0.7					15 0.6	4 0.5	29 0.5	1218 4.5		18 0.96
Intestine Transplants P.M.P				9 0.1										1 0.1		69 0.3		

(*) Heart-Lung Transplants P.M.P Included
(**) Living Donors Included

E.T: Eurotransplant
Germany
Austria
Belgium
Luxemburg
The Netherlands

Sk.T: Scandiatransplant
Denmark
Finland
Norway
Sweden

E.F.G: Etablisement Francaise Des Greffes
I.S.S: Ostituto Superiore Di Sanit

TABLE 3. *Stages of organ transplant procurement*

Group Collaboration	Stage 1 Determination and Referral	Stage 2 Confirmation of Brain Death and Consent Taking	Stage 3 Donor Evaluation	Stage 4 Donor Control and Care	Stage 5 Organ and Tissue Removal
Needed specialties in transplant process: - Specialist in special care - Anesthesiologist - Coroner - Medical examiner - Internist - Immunologist – Pathologist - Pharmacologist - Radiologist - Transplant surgeon - Social worker - Transplant coordinators - Distribution unit of transplant organ - Nephrologists, Urologist - Neurosurgeon	- The patient is hospitalized and all measures are taken to protect his/her life - Probable brain death is detected following primary evaluation - OPU is informed about the case with severe brain injury - Coordinators and team of brain death confirmation begin their evaluation: Time, Date, Weight, Height, Blood grouping	- Brain death is recorded as Time and Date - The physician informs patient's family of his/her brain death - Emotional support from family is conducted - Coordinators explain organ donation for the family - The family accepts donation - Coordinators prepare a signed consent with medical and social history - Representative of forensic medicine is informed - Representative of forensic medicine issues legal authorization for donation - Surgical team for organ removal is informed	- Blood sampling before and after blood transfusion for serologic tests: CMV-VDRL-Hepatitis-HIV-RPR-HTLV I - Useing lymphatic node or blood sampling for typing tests - Informing surgical and anesthetic teams of an early organ removal and transplantation - Lung measurements in chest X ray by coordinators - Cardiovascular consult - Measuring circumference of chest and abdomen - Pulmonary consultation (bronchoscopy cardiac angiography (male over 40 and female over 45)	- Arterial access/ECG monitoring - 2 IV access/BP monitoring - CVP line, Swan-ganz, NG tube, pulse oximetry, Foley catheter, capneography - The reciepiant is selected, transplant team is informed - Urine volume is kept on 100 cc/h - BP is kept 100 mmHg - PaO_2>100 is maintained - Temperature is maintained between 36.5 and 37.5 degrees C	- To prepare the patient for operating room - Intravenous access – pumps - CVP line – O_2 - Ambubag - Peep valve - arterial access - Blood for infusion - Portable monitoring - Pulse Oximetry - Temperature probe - Sending to operating room Operating room nurse: - To review consent form - To review documents of brain death confirmation - To control identification band of patient 1- To select proper organs 2- Ventilator is stoped following aorta clamp 3- Organs are kept in proper and cold solution 4- The organ is transported to transplantation ward 5- Tissues are removed following vascular organ removal 6- Fluid warmer × 2
Diagnostic tests and measures	- The patient is in deep coma - Not to use drugs which weaken CNS - No hypothermia (under 32 degrees) - No metabolic, toxic and endocrine disorders - Complete arrest of automatic respiration - Not to use neuromuscular inhibitor drugs - Detecting the cause of coma - No automatic movement - No response to painful stimuli - No iris reflux - Negative caloric test - Negative gag reflux - Positive apnea test - Performing isoelectric EEC twice with an interval of 6 hours and a duration of 20 minutes - Consistent signs for 24 hours - 72 hours preservation for children under 5-year - No doll's eye - No reaction to cornea stimulation	- To study the results of performed tests - To study hemodynamic condition	- Blood biochemistry - CBC (diff) – U/A-U/C- antibiogram - PT,PTT - ABO- Rh- Subtype A - LDH- Bil- Alk.P- Blood culture towice (15 minutes to one hour separately) - Sputum gram staining and culture and antibiogram - Type/cross match , packed cell unit - CXR - ABGs - EKG - Echo - Cardiac catheterization if needed - Bronchoscopy if needed - In pancreatectomy: BS - Serum amilaz - Serum lipase - HBs Ag- Alk.P- SGOT - HC Ab, ABGs, SGPT – Cr - BUN LDH CPK mb, Bil (total, direct)	- To study the need for further tests - CXR - Ca, K, Na - Hb, HCT following blood infusion - PT, PTT - BUN, Cr following the correction of fluid deficit Case which need warning: - PT> 14 - PTT > 28 - Urinary output: ☐ < 1ml/kg/h ☐ > 3ml/kg/h - HCT < 30 (Hb < 10) - Na > 150 meq / 1 - Normal urine volume in adults 1ml/kg/h - Normal urine volume in children 2ml/kg/h	- Tests required by surgeon are performed - To coordinate with - Pathologist: to perform liver or renal biopsy if needed - To perform autopsy if required.

TABLE 3. *Continued*

Group Collaboration	Stage1 Determination and Referral	Stage 2 Confirmation of Brain Death and Consent Taking	Stage 3 Donor Evaluation	Stage 4 Donor Control and Care	Stage 5 Organ and Tissue Removal
Respiratory System	Respiratory measures: patients is connected to ventilator Suction every 2 hours Position changing every 2 hours	Apnea test: based on protocol Prediction of decrease of rate in the case of PCO2 > 45 mmHg	- Maximum ventilation to reach at SaO_2: 98-99% - PEEP=5 cm O_2 challenge - FiO_2 @ 100% - PEEP @5×10min - ABGs - Regular control of V/S	5cm H_2o , PEEP Inform coordinators in following cases - SBP< 90 (normal 100) - P < 70 or P > 120 - CVP < 4 or CVP > 12(10-12) - PaO_2 < 90 - SoO_2 < 95% - PWP: (8-14) - To use warm moister when prescribing O_2	Using following items during transplantation to operating room Portable O_2@100% FiO_2 (Fraction of inspired O_2) - Ambubag and Peep valve - Transplantation to operating room. Ventilation is stopped when aorta is cross-clamped and organs become cold.
Treatment		- To maintain temperature between – 36.5^c and 37.5^c by using cold/warm carpet - NG to reduce intermittent suction	- To study the site of NG and output - Exact measurement of weight and length if not have been done formerly.	Normal Na < 150 Normal K > 3.5 PH: 7.45-7.35 HCT: 30% Ca: normal limitation	- To coordinate between surgical teams - To keep hemodynamic stability in operating room - Post-mortem cares at appropriate times
Drug			Medication according to orders	- Fluid therapy: Cristaloid, colloid, blood products (using fluid warmer) - Broad spectrum antibiotics: Cephazolin 1gr/96h - To use vasopressor to SBP>90 mmHg - To study electrolyte disorders: K, Ca, Po_4, My (should be corrected if confirmed) - Hyperglycaemia: to be treated with insulin - Oliguria: to be treated by diuretics - Diabetes insipidus: To be treated by anti diuretics - Paralytics in spinal hyper-reflexia - Methyl prednisolon: 1gr half an hour preoperatively	- To stop diuretics - To use diuretics if needed (lasix 100 mg) - To use heparin 350 U/Kg or by the prescribed dosage - manitol 12.5gr or 6gr/h as infusion - Vencuronium or pancuronium - PGE1 -Chlorpromazine - Amphotrepsin in pancreas donors 50mg in 500^{cc} NS by NG
Required results	- Potential donor is determined - Referral to OPU	The family is aware of donation and their decision is supported	- To evaluate the donor: - To study the required criteria for donation - Ultimate rule out criteria: Extracerebral malignancy + untreatable infection	- Organs desired function should be kept	All proper organs recovered for transplantation

sion of Organ Procurement and Transplant Network (OPTN) and United Network for Organ Sharing (UNOS). Every transplant center cooperates with one of OPO's organizations.[7,8]

The main duties of Host OPO are as fallows:

1- to identify, evaluate, and manage brain death cases,
2- to obtain consent from donor's family and to authorize legal processes,
3- to retrieve organ,
4- to supervise, guarantee, and confirm all conservative, package and organ transfer measures and carry out whole tests and tissue typing and compatibility,
5- to share transplant organs.

Fifteen patients die each day, while waiting for an organ to become available in the United States. More than 75 thousands males, females, and children are enrolled in transplant waiting list. Every 16 minutes one patient joins the list. Only 25% to 35% of those who need bone marrow transplantation will find a match among their family members.[3]

Organ system practices in four major sections under the supervision of Division of Transplantation (DOT) in the Ministry of Health. The main duty of DOT is supervising of these practices. These four sections are as follows:

1- Organ Procurement and Transplantation Network (OPTN),
2- UNOS (a non-profit organization, its center is in Richmond, Virginia State) that was established in 1977 under the state laws. Transplant centers, OPOs, laboratories of tissue compatibility, charity centers, religious, legal, ethical, specific advisory committees, etc. are its members. UNOS covers whole the United States in the yield of procurement and transplantation.),
3- Scientific Registry of Transplant Recipient (SRTR) that follows up and analyses transplant results and survival studies, as well),
4- National Marrow Donor Program (NMDP) that consists of 94 centers of bone marrow donation and 118 transplant wards,
5- Increasing Organ and Tissue Donation (IOTD) that attempts to increase social awareness and public education and professional training, as well as to promote the culture of donation.

Spanish Model in Procuring Transplant Organs[9,10]

The first Spanish transplant coordinator team was established in 1985 in Clinic Hospital in Barcelona. This model was gradually extended to other centers, other areas and the whole country; consequently, an independent department by the name of Transplant Coordinator Department was established in each hospital. This department consists of transplant procurement manager (TPM), transplant coordinators and other staff, who play an important role in increasing organ donation and transplant activities.

Medical care, training, research, and management and the quantity control are the main functions that is managed under the supervision of TPM.

1. Medical Care: Clinical tasks are:

1- to detect potential or possible donors: to find out donation potential in the subordinated area according to the number of ICU beds and brain deaths,
2- to facilitate brain death detection,
3- to supervise donor and to perform organ and tissue compatibility,
4- to interview the family. To observe legal aspects,
5- to coordinate organ and tissue extraction and their distribution.

2. Training and Education: Training is of great concern to TPM. Ideally, training teenagers for donation and transplantation, as well as coordination with all groups and branches, which improve knowledge in the society, have great importance. Training professional groups (physicians, nurses, social workers, ...) for transplantation is one of basic principles.

3. Research and Development: The aims of TPM in the field of research and development are to increase the number of donors and to promote transplant organ and tissue quality, as well as to improve donor detection methods. Also, introducing new subjects such as NHBD (non-heart-beating donor) and the use of marginal donor organs is another aim.

4. Management: The management of resources and different activities in organ donation and transplantation process is one of TPM responsibilities. It includes the detection of required sources (human, equipment, financial and creditable), obtaining such sources and planning for them.

The most appropriate place for the activity of organ transplant procurement unit in Spain model are intra-hospital departments, which act separately from transplantation wards.

In this model, the needed number of TPMs varies from one to five, based on potential donation capacity (30 to 60 brain death pmp) and practical donation (1 TPM per 12 practical donor). Effectiveness in a transplantation system is identified by donation rate, number of transplantations, and patient and graft survivals, which are dependent on the role of TPM.

Other Models in Spain

In addition to the above mentioned general models of transplant organ procurement organization/unit, another structure also exists.[9] In this method, organ procurement is performed by a group of staff practiced at transplantation ward. This model was limited to some transplantation wards and is not popularized in different countries.

Transplant organ procurement system in Japan

Although the debate on organ transplant was started in Japan at public level and specialized scientific circles after performing first heart transplantation in 1968 in Saporo University three decades ago, systematic activity in transplant organ procurement began in 1995 by the establishment of Japan Kidney Transplant Network. This network developed into Japan Organ Transplant Network following the approval of organ transplant law in 1997.[11]

Patients were obligated to travel to other countries such as China to receive transplant organ before the approval of the above mentioned law and because of limited organ transplant from living donors and legal impediments in using organs of patients with brain death and cadavers.[12]

Characteristics of Organ Transplant Law in Japan

This law, which was approved in 1997, is only applied for cadaver organ transplant and cases with brain death and does not include living donor.[13] Living donor transplant currently follows the obligations of Japan Organ Transplant Society.

Other Characteristics of this Law

1- Decision card for organ donation: Patient's definition of death (respiratory arrest or complete heart and brain arrest), agreement or disagreement for organ donation and the kind of organ, are included in this card. There is a place for donor signature and family signature, as well.
2- Consent: According to the above-mentioned law, patient consent, in addition to his family consent, should be included too. Thus, if organ donation card is only signed by organ donor with no signature of donor family, this card would not be legally valid. In addition, a separate consent form is obtained from patients' family.
3- Age limitation for organ donation: Organ retrieval from children under 15 years is forbidden according to Japan organ transplant law; therefore, children's organ donation card would be invalid. Japan constitutional law declares that children under 15 years can not make such decisions. Thus, children in need of receiving transplant organ could not find appropriate organ in many cases. Parents have no right too in this regard, while it seems that decision making in organ donation from children with brain death could solve the problem of organ transplant in kids.[14]
4- Forbidding any organ trafficking as well as necessary prediction for any violation has been regarded in this low too.

The Role of Organ Transplant Network

According to the law, duties of organ network, which is a non-governmental and nonprofitable organization, are as follows:

1- to provide general training in organ transplant and donation in the society,
2- to distribute decision card for organ donation,
3- to collect data about organ donation,
4- to inform the family of patients and to perform legal process of consent taking,
5- to carry out laboratory tests for donors,
6- to allocate organ,
7- to coordinate between organ donor and recipient hospitals,
8- to transfer transplant organ,
9- to provide special advice to donor families, following donation,

This network currently consists of 7 main centers and one minor center at Japan and its activities are supervised by direct supervision of Ministry of Health and it is mainly an executive body for organ transplant.[15]

However, six years after the approval of organ transplant law in Japan, this has not been welcomed in Japanese society due to social and cultural believes. Thus, despite high technical and scientific potentials in performing organ transplant, only 22 organ transplants has been conducted from brain death donors, while 13000 patients has been recorded in waiting list.

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