

see commentary on page 625

The Iranian model of living renal transplantation

Mitra Mahdavi-Mazdeh¹

¹*Iranian Tissue Bank Research & Preparation Center, Tehran University of Medical Sciences, Tehran, Iran*

Organ shortage for transplantation remains a worldwide serious problem for kidney patients with end-stage renal failure, and several countries have tried different models to address this issue. Iran has 20 years of experience with one such model that involves the active role of the government and charity foundations. Patients with a desperate demand for a kidney have given rise to a black market of brokers and other forms of organ commercialism only accessible to those with sufficient financial resources. The current Iranian model has enabled most of the Iranian kidney transplant candidates, irrespective of socioeconomic class, to have access to kidney transplantation. The Iranian government has committed a large budget through funding hospital and staff at the Ministry of Health and Medical Education by supporting the brain death donation (BDD) program or redirecting part of the budget of living unrelated renal donation (LURD) to the BDD program. It has been shown that it did not prevent the development and progression of a BDD program. However, the LURD program is characterized by several controversial procedures (e.g., confrontation of donor and recipient at the end of the evaluation procedure along with some financial interactions) that should be ethically reviewed. Operational weaknesses such as the lack of a registration system and long-term follow-up of the donors are identified as the 'Achilles heel of the model'.

Kidney International (2012) **82**, 627–634; doi:10.1038/ki.2012.219; published online 6 June 2012

KEYWORDS: clinical epidemiology; ESRD; kidney transplantation; statistics; transplantation

Living unrelated renal donation (LURD) is still a hot topic in professional debates around organ shortage for transplantation. The still increasing demand for renal transplantation brings the subject of LURD to the core of medical caregivers' attention confronting them with a number of controversial aspects of this entity topic, requiring ethical consideration.

Transplantation societies and the World Health Organization try to prevent unethical practices by formulating guidelines for the organ distribution and donation of unrelated living kidneys. The declaration of Istanbul on Organ Trafficking and Transplant Tourism 2008 is among the latest common global efforts to convince different countries to agree on a common approach to stop commercial exploitation and stimulation of deceased donation.¹

Socioeconomic differences, as well as differences in cultural values, religious beliefs, legislative barriers, and lack of the required infrastructure between countries, may prevent setting standard international guidelines. In this short review, the positive and negative aspects of the Iranian LURD are discussed.

HISTORY OF TRANSPLANTATION IN IRAN

Iran, located in southwest Asia (part of the Middle East), covers an area of 1.65 million km² and has nearly 75 million inhabitants. It is characterized by a very young population. One-fourth of the population is younger than 15 years with a life expectancy at birth of 72 years. It is one of the largest OPEC (Organization of the Petroleum Exporting Countries) oil producers. The gross domestic product per capita was estimated in US\$4520 for 2009, but is subject to highly fluctuating international oil prices. Unemployment was 10.5% of total labor force and literacy rate in people older than 15 years was 85% (2008 estimates). Total health expenditure share is 5.5% of gross domestic product. Under-five mortality rate was 26 per 1000 live births (2010 estimate).²

The establishment of hemodialysis facilities goes back more than 30 years.^{3,4} In 1974, Ministry of Health and Medical Education (MOHME) established the first dialysis center. Gradually, the number of patients on hemodialysis increased from 587 patients in Tehran in 1991 to more than 25,000 (360 per million population, pmp) in 2006. Although the first kidney transplantation took place in 1967, only 112 renal transplantations were performed until 1985. The limited transplantation activity between 1979 and 1984 was in part due to the circumstances of the 1979 revolution that

Correspondence: Mitra Mahdavi-Mazdeh, Iranian Tissue Bank Research & Preparation Center, Tehran University of Medical Sciences, Tehran, Iran. E-mail: mmahdavi@sina.tums.ac.ir

Received 6 March 2012; revised 28 March 2012; accepted 5 April 2012; published online 6 June 2012

caused Iranian assets to be frozen overseas and the Iran–Iraq war. At the time, the MOHME allowed and funded patients to receive transplantation abroad. Any dialysis patient who was able to present the required documents and a potential living related donor at a center overseas (mostly in the United Kingdom) willing to operate the patient could apply for the governmental funding.^{5,6}

In 1985, aiming to solve the problem of long waiting list, two renal transplantation centers were established and 274 renal transplantations were performed in the country within the two following years. In 1988 a government regulated and funded LURD program was set up and approved by the Council of Guardians. Adopting a universal transplantation program during the 8-year war was an outstanding achievement and blessing for patients with no access to dialysis and for health authorities with limited budgets to set up new dialysis centers and expanding or maintaining existing ones.^{5,7,8} The ‘Gift of Altruism’/‘Rewarded Gifting’ governmental scheme to any kidney donor was approved by the Board of Ministers in early 1997.^{7,9} Dramatic increase in the number of renal transplantation centers from 2 in 1985 to 13 in 1992¹⁰ and 23 in 2001⁴ resulted in almost disappearance of waiting list in 1999.^{6–8}

Shortly after the adoption of living unrelated transplantation program, the MOHME decided that transplant centers were not allowed to perform transplantations using a kidney from candidates with different citizenship than Iranian. The suggestion for an amendment of the legislation came from transplantation authorities to prevent wealthy patients from neighboring countries or refugees (mainly Afghans) who lived in the country from using the opportunities offered by the Iranian model.^{4–7}

The next major progress was the legislation of ‘Organ Transplantation and Brain Death Act’ in 2000, legalizing brain-dead organ donation.⁹ Until that year, a total of 7187 renal transplantations were performed from living unrelated

donors upon the implementation of LURD program.⁸ Introduction of laparoscopic donor nephrectomy in 2000 made transplantation cheaper and safer.¹¹

Following the ‘Organ Transplantation and Brain Death Act’ legislation, a virtual network was launched and it gradually spread all over the country consisting of 13 organ procurement units, all located in approved university hospitals and 18 brain death identification units. The brain death identification units in cities without transplantation centers refer cases to actual transplantation centers. After performing a number of medical tests, consultation with specialists and an electroencephalogram, compatible with brain death, the donor is transferred to an intensive care unit of the organ procurement units.

The declaration of brain death is signed by five MOHME appointed physicians (consisting of an internist, a neurologist, a neurosurgeon, an anesthesiologist, and a forensic medicine specialist) after carrying out neurological tests and a confirmatory electroencephalogram. According to the law, the first-degree relatives of a brain-dead donor should be informed about the situation and be offered the option of donation. Written approval of first-degree relatives of potential donor is necessary if consent for organ donation had not been provided while the person was alive.^{4,12}

MEDICAL INSURANCE COVERAGE AND NATIONAL FORMULARIES FOR IMMUNOSUPPRESSIVE DRUGS

All patients who need renal replacement therapy (RRT), including renal transplantation, are classified as ‘patients with special diseases’ and are provided governmental medical insurance which reimburses dialysis and transplantation. Hence, different modalities of RRT are free of charge and accessible for all irrespective of age, sex, and financial situation in Iran (Figure 1). Furthermore, the government imports and subsidizes essential immunosuppressive drugs and insurance agencies cover the remaining cost of immunosuppressive drugs.^{3,4}

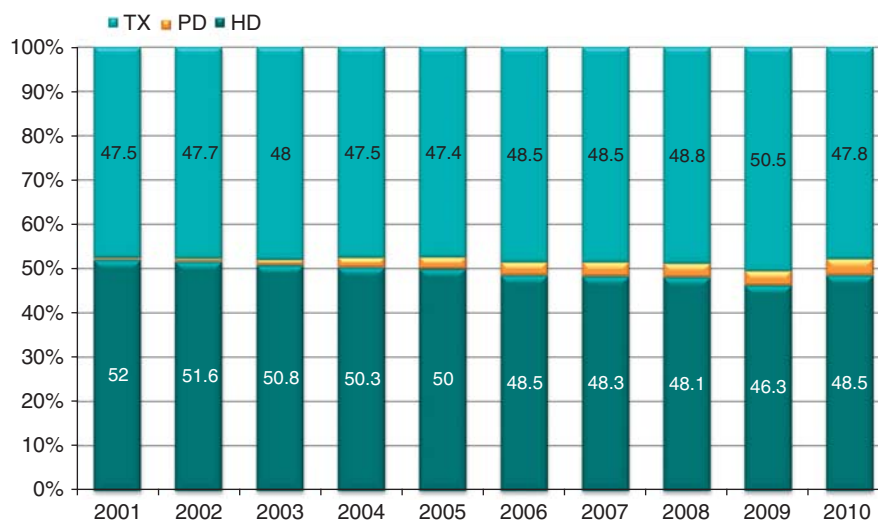


Figure 1 | Renal replacement therapy trend in Iran between 2001 and 2010. HD, hemodialysis; PD, peritoneal; TX, transplantation.

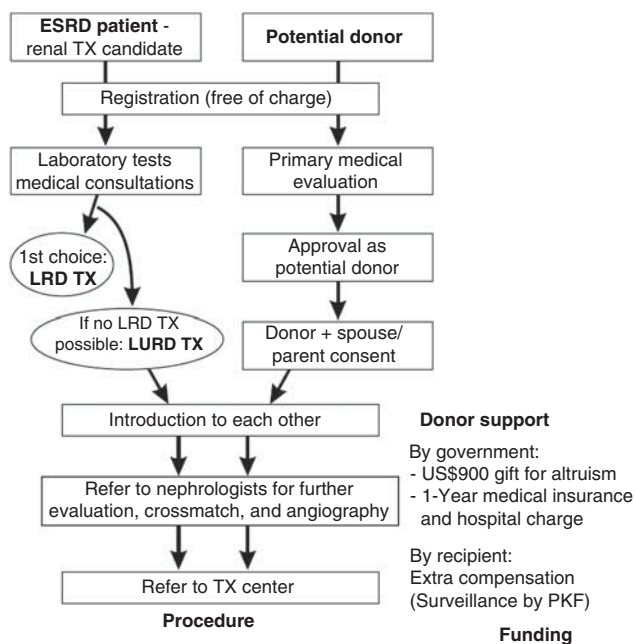


Figure 2 | The process of living unrelated kidney donation and transplantation. ESRD, end-stage renal disease; LRD, living related donor; LURD, living unrelated renal donation; PKF, Patients Kidney Foundation; TX, transplantation.

At first the immunosuppressive protocol consisted of generic azathioprine, which was later replaced by mycophenolate mofetil in 2000. A domestic pharmaceutical company started producing mycophenolate mofetil under license of the Roche Company in 2003 and later the generic form of cyclosporine was added to its production list. Sirolimus is prescribed from 2008 and also subsidized.⁹

THE PROCESS OF UNRELATED KIDNEY TRANSPLANTATION

The caring physician explains the different treatment modalities and priority of related donation to all patients who need RRT (Figure 2). If a patient chooses or has to rely on unrelated kidney transplantation, he/she will be referred to the Iranian Patients' Kidney Foundation. It was established in 1978 and has currently 137 branches all over the country. It is mainly run by volunteering patients who suffer from chronic kidney diseases and is also called the Dialysis and Transplant Patients Association. Any 18- to 35-year-old person who wishes to donate a kidney is referred to the foundation for registration, free of charge for both donors and recipients.^{6,10}

The primary evaluation, including routine medical laboratory tests and imaging, was assessed by physicians working in the Patients' Kidney Foundations' clinics. The second step consists in obtaining an informed consent from both donors and their next of kin upon provision of a national identification card to the foundation. Then the potential donor and recipient are introduced to each other. For the final evaluation, they are referred to a nephrologist who will check for issues in detail. When the donor has some borderline laboratory

data, he will be barred from organ donation. It should be mentioned that human leukocyte antigen typing is not performed for LURDs, only a white blood cell cross-match is routinely performed.^{5,6}

Evaluation for subtle family pressure or coercion is particularly considered when the potential donors are female (related/unrelated). They are informed by the nephrologist that at any time the excuse of medical unsuitability can be provided if they do not wish to donate.

According to the national kidney transplantation registry, male to female donor ratio has been 1.6:1 in more than 21,000 related and unrelated kidney transplantation.⁴

The third step consists in a negotiation between the donor and the recipient concerning an extra compensation for the donor. It takes place at the foundation where a private space is provided for them. The foundation does not keep records of the agreed money for exchange and has no role in the exchange process. Furthermore, the foundation maintains some control on the issue by introducing another potential donor to the recipient if a donor asks for an unusual amount of money. The latter may also be omitted from the list of potential donors. It should be pointed out that although the amount of additional rewards from recipients to donors is not regulated they are at least not subjected to abuse by brokers, as recipients and donors meet face to face. After the operation, the donor presents the documents of the transplantation to the designated charity office called Charity Foundation for Special Diseases (CFSD) to get the 'gift of altruism' and 1 year of medical insurance. The money is allocated from governmental funds but it is paid through CFSD.^{7,13} Transplantations are performed in university hospitals and its expense is paid by health insurance agencies and MOHME (Figure 2).⁷ Recently in a pilot study a fixed amount of money (approximately US\$3500) was deposited with the Patients' Kidney Foundation as payment from the recipient before the transplant was performed; it was paid to the donor after the procedure. The results of this pilot study have not been officially reported from the Iranian government.

PROGRAM SURVEILLANCE

Organ transplantation in Iran such as any other health programs is under the supervision of the MOHME. Each university of medical science has the responsibility to oversee and regulate the management in the medical centers belonging to their province, according to guidelines of MOHME. One of the secretarial offices of the university of medical sciences is engaged in coordinating different modalities of RRT affairs. One of their tasks is to send a complete list of the data and a detailed report of the expenses related to deceased organ procurement of the transplant centers, covered by the related university of medical science in the province, to MOHME. Ten percent of the kidney transplantation fee is covered by MOHME (90% by health insurance companies). They also dispatch updated national guidelines to affiliate centers and especially do surveillance on distribution of immunosuppressive drugs.^{4,9}

MEDICAL CONCERNS IN LIVING UNRELATED DONATION

Short-term risk

The main short-term risk for the donors can arise mainly from the surgery. An overall mortality risk of 0.02–0.03% has been reported. The major and minor perioperative complications attained 1.5% and 8.5%, respectively, in Iran.¹⁴ Kasiske investigated the risk of kidney donation through published reports between 1970 and 1979,¹³ 1980 and 1989,¹² and after 1990²; he found two deaths out of 3639 kidney donations (0.05%), of which one donor was 76 years old at the time of surgery. He also mentioned to the 0.03% risk of mortality found in other surveys from UNOS-approved centers and the different risk in different centers. It seems that the overall mortality and major morbidity were not estimated to be more than 0.03% and 0.23%, respectively.¹⁵ Segev *et al.*¹⁶ also found surgical mortality of 3.1 per 10,000 live kidney donation in the United States, which has not been changed over the past 15 years. It seems the rates of short-term complications in Iran are comparable to other international studies. By the introduction of laparoscopic donor nephrectomy, the procedure became more safe with lower morbidities compared with open surgery. An important point is the fact that all transplantation teams in Iran belong to university hospitals licensed by MOHME, offering medical management by well-trained hands used to functioning as a team.^{4,6}

Long-term risks

Studies have repeatedly shown that the risk of developing end-stage renal disease (ESRD) was 0.3–0.05%^{17,18} and that survival of the donors who have been properly screened is similar, if not superior, compared with the general population.^{15–18}

In the Ibrahim *et al.*¹⁷ study, 12.2 ± 9.2 years after donation the prevalence of hypertension and microalbuminuria were 32.1% and 12.7%, respectively. They have been 37.5% and 10.4%, respectively, in the only short-term medical follow-up (17.2 ± 5.0 months) in the Iranian donors.¹⁹ Lack of long-term donor follow-up in Iranian model is one of the major weak points of the system. In view of the major ethical principle ‘do not harm’ and as health-care providers, we should not only control the short-time risks but should also take lifelong care of any possible comorbidity related to donation of an organ. On two occasions in 2004, 500 donors were called and invited to have health examinations in one of the referral transplantation hospitals in Iran; just six patients responded (personal communication with Dr Savaj).

ETHICAL CONCERNS IN LIVING UNRELATED DONATION

It is apparent that in the Iranian model several serious ethical problems of unrelated kidney transplantation, as frequently observed elsewhere in the world, have been successfully managed: no brokers, no transplant tourism looking for commercial organ transplantation, a law regulating the same citizenship between recipient/donor, no financial benefit for transplantation teams, and informed consent not only from recipients but also their next of kin (Table 1).^{5,7,9}

There are, however, still some serious concerns to be addressed:

(1) Financial connection between donor and recipient

The main question, which has been a source of major concern by international transplantation experts, is the direct payment of the donor by the government and an additional amount of money given by the recipient to the donor defined in the literature as a vending relationship.

Payment in this model consists in two components: first is monetary compensation for the life-saving act of donation and second is the direct method of payment by the recipient. Each has its own positive and negative points.

(A) Monetary compensation for donation: it is written in the literature that once poor people are in the market to sell a kidney, such sales will be coercive even in the context of informed consent.^{20,21} (Although, nobody denies that the most important motivation for donation in the Iranian model is not emotional/altruistic, nor does anyone deny that most of the donors belong to the low socioeconomic class.²²) There are

Table 1 | Strategies of Iranian model to solve the dilemma of sale vs. donation

Legal approval of compensation for donor and transplantation expense in the hospital:

- Saving lives of many ESRD patients especially before the Brain Death Act
- Waiting list omission
- Complete medical and psychological examination of donors in the hospital, in addition to routine outpatient evaluation process
- No middle man/broker or travel to the country to buy kidneys
- No financial benefit of transplantation team
- Development of BDD program and its progression (increasing experience of transplantation centers)

Same nationality of donor/recipient:

- Donors cannot seek the highest possible price (no foreign patient can enter the system)
- Rich and poor can be transplanted

Supervision of Patients' Foundation on donor motivation:

- Getting informed written consent from donor and next of kin
- No coercion of donors
- No exploitation of the poor
- Donor age > 18
- Separation of scientific responsibilities from ethical ones
- Protection of fundamental doctor–patient relationship

Transplantation centers in academic hospitals licensed by the MOHME:

- Decrease donor harm to the least
- Development of newer and safer approaches possible (e.g., laparoscopic nephrectomy)
- Complete medical and psychological examination

Sharing with recipient in donor compensation:

- Direct financial connection between donor/recipient (negative point)
- Donors do not like to be known (negative point)
- Transparency of system (no abuse in the system)
- Development of BDD program and its progression (by redirection of the budget)

Lack of protracted/long-term follow-up of donors

Abbreviations: BDD, brain death donation; ESRD, end-stage renal disease; MOHME, Ministry of Health and Medical Education.

two points, however, which deserve comment; autonomy, and socioeconomic, situation of donors in comparison with recipients.

(i) Autonomy: first of all, it's very well documented that as long as poverty exists, individual effort to change such a condition will occur. Everybody has the right to overcome his/her problems by socially acceptable approaches. In the Iranian LURD model nobody interferes in the decision making of the poor to take or not a relative higher risk that the rich do not normally take. Preventing this act may mean paternalism and only deprive them from the opportunity to improve their socioeconomic situation.^{23,24} For example, the ratio of those who belong to lower socioeconomic groups in the US military service, particularly in the combat units, is high and volunteering is encouraged by some national rewarding system.²⁵ Similarly, there is no objection to people who choose to work as firefighters or in the mining business, conditions well known to be at relative high risk for injury as well as death. In our view, poverty cannot interfere with individuals' autonomy. As long as the donation is not coercive, it is the responsibility of the community to respect the dignity of the human (as is done for firefighters, soldiers, and policemen who take high-risk jobs to protect others).²⁴

In the Iranian model, there is no coercion from the recipient's or Patients' Kidney Foundation's side as the donor is referred to the foundation by his/her own will. Obviously the economic situation influences such decision.

In altruism-based systems, the bioethical principles (autonomy, beneficence, justice, and nonmaleficence) look balanced as the donor is satisfied by participating in changing the life of the recipient by improvement of his/her health and is highly appreciated in the social environment. Why should the aspirations of the unrelated donor, who not only helps to partly solve the problem of his/her own family (by monetary compensation) but also to save the life of an ESRD patient by taking a risk comparable to that of an unpaid donor, not be duly appreciated?²⁴

(ii) Socioeconomic situation of donors compared with recipients: there are three different studies describing the donors' socioeconomic status and the donors' interaction with their 'donation act' (Table 2). Unemployment has been reported to be 22.5,²⁶ 29%,²² and 15%²⁷. As expected, financial motivation was the main driving force for donation of an organ with the money spent for medical purposes (the need for hospitalization of a family member), to solve personal/family problems, to pay back a debt, or for paid military service

Table 2 | Donor socioeconomic status in Iran

	Heidary Rouchi ²⁶ (%)	Malakoutian ²² (%)	Ghods ⁵ (%)	Zargooshi ²⁷ (%)
Sample size (person)	600	478	500	100
Location of research	17 Centers	30 Center	30 Centers	One city
Time of filling questionnaire	Before discharge			≥ 24 mo of tx
Age (mean ± s.d.) years	28.0 ± 5.2	27 ± 4.8		31 ± 12
Gender: male/female	495/105=4.7	408/70=5.8	451/49=9.2	67/33=2
Related/nonrelated	32/568	0/478	0/500	0/100
Married	468 (79%)	82%		(90)
Economic status	Mean monthly income: US\$ 175.0 ± 68.5 (43.5–380.4)	< (2\$/day): 297 (62%)	Unable to afford average housing, food, and college expense of their children: 420 (84%)	
<i>Job</i>				
Unemployed	118 (22.5)	139 (29)		(15)
Full-time	146 (27.9)			(16)
<i>Education</i>				
Illiterate	(4.6)	(2.7)	(6)	(29)
6–12 years	(88.9)	(90.8)	(87.8)	(71)
University degree	(6.5)	(6.5)	(6.2)	0
<i>Motivation</i>				
Purely financial	224 (37.3)			(43)
Financial+altruistic	365 (60.8)		—	(57)
Purely altruistic	11 (1.9)			(3)
<i>Donor feeling</i>				
Complete/relative satisfaction	588 (98)	435 (91)		(29)
Regret	9 (1.5)		—	(51)
Indifference	3 (0.5)			(20)
Do they encourage it to others?		53%		
Willing to be informed of transplant outcome	457 (76.2%)			
Willing to make connection with recipient	400 (66.7%)			

exemption.²⁶ The situation is in sharp contrast with socio-economic status of the vendors in Pakistan as a typical example of commercialism in transplantation, who in 90% of the cases were illiterate (Iranian donors illiteracy rate is less than 6% in most studies), live on less than US\$1 a day (more than 94%), and have no idea concerning the amount of money they should receive.^{5,22,26,28}

Nevertheless, most economic situations of the donor and recipient are not that different from those described by many renowned ethicists. Poverty has a broad definition. A study on the economic situation of 500 recipients in Iran defined 50.4% of the recipients as poor (those who could not afford average housing, food, or college training for their children). Those who were able to afford only average housing, food, and college training of their children, defined as the middle class, represented 36.2% of the transplanted patients. Surprisingly, just 13.4% were classified as wealthy.⁵ In another study of 247 patients on hemodialysis in Tehran, 29.8% had to retire due to ESRD and another 26.9% were unemployed, which emphasizes the fact that the economic situation of the recipients is far from being clearly superior to the average donor in the country.²⁶ Charity organizations and generous people not only actively support these patients' renal transplantation expenses, but also help them in buying some drugs not covered by insurance.⁵⁻⁷ In the suggested model by Rizvi, participation of government and donations covering the expense of the operation and immunosuppressive drugs were the reasons for transplantation program success in the Sindh Institute of Urology and Transplantation, which helped many poor patients to be transplanted.^{29,30}

In another study on 2630 hemodialysis patients, only 7% of those who were medically eligible for transplantation were registered on a brain-dead donor waiting list in Tehran province in 2005. This study emphasizes that even low-income patients (as most patients on hemodialysis did not have a job) took their time to evaluate the new offered modality of brain death organs.^{26,31} Iranian potential recipients need to be convinced by the successful outcome of the brain death donation (BDD) program before they decide to register eagerly for the brain-dead donor waiting list. If the law of same citizenship had not been approved in the country, wealthy candidates from high-income countries would have been in the scene with appealing proposals for donors (commercial organ transplantation) and the Iranian patients would not have any choice to consider this option of treatment. It is very well documented that the major financial source of organ trafficking in most developing countries is from recipients from developed countries who want to avoid, by all means, the years long waiting time before being transplanted.^{23,24}

(B) Direct method of payment from recipient: it seems that if governments or any other controlled health-related organizations offer to pay all the costs, including a reasonable compensation for the act of donation, not only the questionable donor/recipient relationship will fade away but

also the donors' feelings regarding their unequal benefit (financial incentive) in comparison with the recipients (lives) would be resolved.^{5,8} Such an approach could be applied in high-income countries with the capabilities for practicing other expensive ways to increase donation rates, including desensitization protocols for ABO blood group-incompatible/positive cross-match pairs, marginal donors, and organs from cardiac-dead donors.

Owing to the inadequate budget (due to higher percentage of its redirection to BDD program) allocated to the LURD program by the Iranian government, the involvement of the recipient in direct donor compensation could not be prohibited. This donor compensation takes place with transparency without manipulation of middlemen, but at the expense of acquaintance between the donors and recipients.

(2) Available sources of kidneys and the threat of postponing or even terminating deceased or related organ donation

The transplantation program of Iran has been encouraging transplantation from unrelated sources to overcome its shortage in the early 1980s. Hemodialysis was not accessible widely and brain death organ donation had not been approved. It is important to know that law of Gift of Altruism was approved in 1997 subsequent to the rejection of Brain Death Organ Donation Act in the parliament in 1995. Overcoming the wide gap between organ demand and supply by a realistic approach such as monetary incentives facilitated 7187 renal transplantations from living unrelated donors to be performed till the legislation of BDD in 2000.⁸

After that it was time to revise the existing strategy. Health professionals had to persuade the family members of potential brain-dead individuals to donate organs. They also had to inform the public and the dialysis population about the BDD opportunity, despite the general belief that from cultural (having an organ of a dead person in the body) and medical points of view (longer ischemic time), it was not an optimal source for kidney transplantation.

The budget for BDD program has been partly provided by the redirection of budget from LURD program. In addition, it is relevant to know that from 1990 to 2001, Iran had a multi-exchange-rate system by which most essential supplies were imported, averaging 1750 rials per US dollar. In March 2002, the multi-exchange-rate system was converted into a rate of 7900 rials per US dollar. It means that as the governmental financial incentive for kidney donation has not been changed over years, its value decreased from more than US\$3500 in late 1990s to US\$1265 in 2002 and to US\$900 2011.

It may be argued that if the amount of official governmental incentive had risen in parallel to the value of the state's currency, there would have been no need for the participation of the recipient in the overall compensation and even a non-directed (altruistic anonymous) LURD could be have been promoted.

In the brain-death organ procurement program, 65 000 000 rials (US\$6119) is allocated to the organ procurement unit for each brain-dead donor, and if two or more organs are recovered from the BDD, this amount would increase to \$6453 and \$9034. This amount does not include what is paid to the transplantation centers for covering the transplantation procedure expenses.

Obviously, the BDD program needs more elaborated infrastructure as in most western countries. However, they do not exist in many developing countries with their limited number of specialists and centers. Training transplantation teams was and still is a challenge, which mainly needed teamwork at odd times of the day/night and even on holidays. What helped Iranian transplant teams and patients in managing the current transplantation program was their experience with a high number of transplantations through the Iranian model: many surgery, urology residents, and nephrology fellows were trained in transplantation wards during their education. As a result, management of transplanted patients changed to a routine instead of a complicated exceptional procedure. The immunosuppressive drugs became accessible at reasonable prices and some of them were even produced locally. Patients get used to this sophisticated process, going along with repeated laboratory tests and imaging procedures at regular intervals. Although the results are encouraging, the program is still in its infancy and there is a long way to carry on.

In Iran, the potential BDD is transferred to the intensive care unit of organ procurement units, by the coordinating team. This transfer is mandatory because the technical expertise and human resources for managing the donor's medical condition until harvesting are available only in university hospitals.

As Figure 3 shows, although the absolute number of transplantations increased from 1421 in 2000 to 2285 in 2010, the 86% share of LURD in 2000 (20.1 pmp) decreased to 75% in 2006 (23 pmp) and 69% in 2010 (21.8 pmp). This change was mainly due to a substantial increase of BDD (2.2% in 2000, 0.4 pmp to 26%, and 7.9 pmp in 2010).³² The Iranian model is a clear answer to the many times formulated criticism of a regulated LURD program prohibiting the development of a deceased donor renal transplantation program, even in developing countries.³⁰

The problems with BDD seem to originate from infrastructural deficiencies and cultural barriers (73% refusal rate of BDD families) and are not due to the availability of the paid kidney donation program.³³ In contrast with the results calculated by Harmon *et al.*,²⁰ the success of the many western countries', and especially Spanish, BDD program cannot be expected in the immediate future from many developing countries including Iran. Their success is not just due to passing the presumed consent law, but it is because the hospitals are provided with specific budgets, qualified staff, and sensitizing programs for the general population aiming at better acceptance of BDD programs and not to the least their years-long tradition and experience. We should not forget that cultural obstacles are not easy to overcome. For

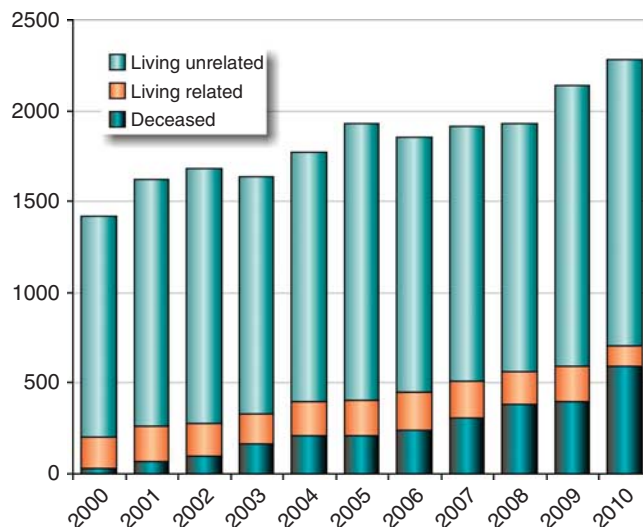


Figure 3 | Kidney transplantation practice after 'Organ Transplantation and Brain Death Act' legislation in Iran.³²

example, only 86 cases of organ donation from brain-dead donors have been reported since the Organ Transplant law passed in Japan, a fully-developed country, in 1997.³⁴

(3) Some critics believe that poor donors are generally underinformed and their so called informed consent should be set aside

In the donation process, it is particularly difficult to distinguish decisions made under pressure from those made freely. Informed consent is to satisfy the medical team that the donor is able to make a rational decision on the basis of his/her free will. Although we think that familial relationship does not guarantee the altruistic donation, the informed consent from the next of kin of donor in the Iranian model is an attempt to make LURD the choice a consensus decision of the family. Second, by the involvement of a not-for-profit charity-based system in the process of getting the informed consent, the role of a medical team responsible for the medico-scientific approach and evaluation is separated from the identification of the donors' motivation and verification of the informed consents. The physician's authority to veto a potential candidate for medical reasons is fully operative.

Future possible steps forward to improve the system are as follows:

(1) Is it appropriate to ban the LURD at this step?

Some may believe that because of the promising way of the BDD program, it is time to set aside the LURD. If we consider the situation of limited available facilities of different modalities of RRT, the increasing rate of ESRD incidence globally and locally (prevalence and incidence rates of ESRD in Iran increased from 238 pmp and 49.9 pmp in 2000 to 357 pmp and 63.8 pmp in 2006, respectively),³ and the current approach of many countries in response to shortage of organs to encourage live donation, such a decision would be unrealistic and unreasonable. Furthermore, removal of any form of pressure on members of the family by the patient or as a

moral self-obligation by potential donors was and is one of the advantages of Iranian model.

(2) It can be argued that we should focus as much as we can on publicizing the BDD program and, little by little, it may compete with LURD program. It may seem logical but it should not be forgotten that the incidence of ESRD is increasing worldwide and especially in developing countries. Increasing the rate of BDD cannot keep pace with the increasing number of ESRD patients.

(3) More support from the government for payment to donors and elimination of the donor-recipient financial relationship can solve some of the ethical concerns of the model.

(4) It cannot be ignored that the LURD program had a great impact in development of the necessary infrastructure for a successful BDD program. However, the most essential step to make the BDD program to materialize was the passage of the law covering this program in the parliament. Ten years of experience with scientific, social, and public educational efforts made most people of the country familiar with the issue and decreased refusal rate of BDD in families. It seems that it is time for experts to work for the next step forward to another national policy of presumed consents (assumed to have given their consent to organ donation unless they officially record their unwillingness during life) of all residents of the country. By this law, coordinators can approach mourning families easier and the family uncertainty in decision making could be overcome. It may increase the donation rate from BDD at least two times.

DISCLOSURE

The author declared no competing interests.

REFERENCES

1. Delmonico FL. The development of the declaration of Istanbul on organ trafficking and transplant tourism. *Nephrol Dial Transplant* 2008; **23**: 3381-3382.
2. The World Bank. Data: Iran, Islamic Rep. <http://data.worldbank.org/country/iran-islamic-republic>. 2011 (updated 8 December 2011).
3. Aghighi M, Heidary Rouchi A, Zamyadi M *et al*. Dialysis in Iran. *Iran J Kidney Dis* 2008; **2**: 11-15.
4. Mahdavi-Mazdeh M, Heidary Rouchi A, Norouzi S *et al*. Renal replacement therapy in Iran. *Urol J* 2007; **4**: 66-70.
5. Ghods AJ, Savaj S. Iranian model of paid and regulated living-unrelated kidney donation. *Clin J Am Soc Nephrol* 2006; **1**: 1136-1145.
6. Einollahi B. Iranian experience with the non-related renal transplantation. *Saudi J Kidney Dis Transpl* 2004; **15**: 421-428.
7. Simforoosh N. Kidney donation and rewarded gifting: an Iranian model. *Nat Clin Pract Urol* 2007; **4**: 292-293.
8. Zahedi F, Fazel I, Larijani B. An overview of organ transplantation in Iran over three decades: with special focus on renal transplantation. *Iranian J Publ Health* 2009; **38**: 138-149.
9. Mahdavi-Mazdeh M, Rouchi AH, Rajolani H *et al*. Transplantation registry in Iran. *Transplant Proc* 2008; **40**: 126-128.
10. Simforoosh N, Bassiri A, Amirsari B *et al*. Living-unrelated renal transplantation. *Transplant Proc* 1992; **24**: 2421-2422.
11. Simforoosh N, Basiri A, Tabibi A *et al*. Laparoscopic donor nephrectomy—an Iranian model for developing countries: a cost-effective no-rush approach. *Exp Clin Transplant* 2004; **2**: 249-253.
12. Nozary Heshmati B, Tavakoli SA, Mahdavi-Mazdeh M *et al*. Assessment of brain death of organ donors in Iran. *Transpl Int* 2010; **23**: e7-e9.
13. Larijani B, Zahedi F, Taheri E. Ethical and legal aspects of organ transplantation in Iran. *Transplant Proc* 2004; **36**: 1241-1244.
14. Ghods AJ. Ethical issues and living unrelated donor kidney transplantation. *Iran J Kidney Dis* 2009; **3**: 183-191.
15. Kasiske BL, Ravenscraft M, Ramos EL *et al*. The evaluation of living renal transplant donors: clinical practice guidelines. *Ad Hoc clinical practice guidelines subcommittee of the patient care and education committee of the American Society of Transplant Physicians. J Am Soc Nephrol* 1996; **7**: 2288-2313.
16. Segev DL, Muzaale AD, Caffo BS *et al*. Perioperative mortality and long-term survival following live kidney donation. *JAMA* 2010; **303**: 959-966.
17. Ibrahim HN, Foley R, Tan L *et al*. Long-term consequences of kidney donation. *N Engl J Med* 2009; **360**: 459-469.
18. Fehrman-Ekholm I, Norden G, Lennerling A *et al*. Incidence of end-stage renal disease among live kidney donors. *Transplantation* 2006; **82**: 1646-1648.
19. Azar SA, Nakhjavani MR, Tarzami MK *et al*. Is living kidney donation really safe? *Transplant Proc* 2007; **39**: 822-823.
20. Harmon W, Delmonico F. Payment for kidneys: a government-regulated system is not ethically achievable. *Clin J Am Soc Nephrol* 2006; **1**: 1146-1147.
21. Hughes PM. Constraint, consent, and well-being in human kidney sales. *J Med Philos* 2009; **34**: 606-631.
22. Malakoutian T, Hakemi MS, Nassiri AA *et al*. Socioeconomic status of Iranian living unrelated kidney donors: a multicenter study. *Transplant Proc* 2007; **39**: 824-825.
23. Friedman EA, Friedman AL. Payment for donor kidneys: pros and cons. *Kidney Int* 2006; **69**: 960-962.
24. Matas AJ. Why we should develop a regulated system of kidney sales: a call for action!. *Clin J Am Soc Nephrol* 2006; **1**: 1129-1132.
25. Monaco AP. Rewards for organ donation: the time has come. *Kidney Int* 2006; **69**: 955-957.
26. Heidary Rouchi A, Mahdavi-Mazdeh M, Zamyadi M. Compensated living kidney donation in Iran: donor's attitude and short-term follow-up. *Iran J Kidney Dis* 2009; **3**: 34-39.
27. Zargooshi J. Iranian kidney donors: motivations and relations with recipients. *J Urol* 2001; **165**: 386-392.
28. Naqvi SA, Ali B, Mazhar F *et al*. A socioeconomic survey of kidney vendors in Pakistan. *Transpl Int* 2007; **20**: 934-939.
29. Rizvi SA, Naqvi SA, Zafar MN *et al*. A renal transplantation model for developing countries. *Am J Transplant* 2011; **11**: 2302-2307.
30. Rizvi SAH, Naqvi SAA, Hussain Z *et al*. Renal transplantation in developing countries. *Kidney Int* 2003; **63**: S96-S100.
31. Mahdavi-Mazdeh M, Zamyadi M, Nafar M. Assessment of management and treatment responses in haemodialysis patients from Tehran province, Iran. *Nephrol Dial Transplant* 2008; **23**: 288-293.
32. Transplant Procurement Management. <http://www.tpm.org>. 2011 IRODaT (updated 8 December 2011).
33. Khoddami Vishteh H, Ghorbani F, Ghobadi O *et al*. Causes and follow-up outcomes of brain dead patients in Shahid Beheshti University of Medical Sciences hospitals. *Pejouhandeh* 2010; **15**: 171-178.
34. Teraoka S. Current status and issues of organ transplantation in Japan). *Nippon Rinsho* 2010; **68**: 2173-2185.