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Paid Donation a Global View, Outcomes of Paid Donation in Iran, Pakistan and Philippines

Nasrollah Ghahramani, MD, MS, S. Adibul Hasan Rizvi, and Benita Padilla

Keywords

donor; incentive; kidney; transplantation; unrelated

Introduction

The first KT in Iran was performed in Shiraz in 1967. Between 1967 and 1985, approximately 100 KTs were performed. To accommodate the large number of patients with no living related donor (LRD), and due to lack of legislation for deceased donor kidney transplant (DD KT), Iran instituted a government-funded compensated living unrelated kidney donation program in 1988 ¹. ESRD patients with no willing related donors are referred to Dialysis and Transplant Patients Association (DATPA), a charitable organization consisting of ESRD patients. Potential donors also register with the DATPA and undergo evaluation in the foundation's clinics ¹. The KT candidates and their LURD are referred by DATPA to the KT teams. DATPA receives no incentives for identifying or for referring the donor-recipient pair to KT teams ¹. KT teams belong to university hospitals and all expenses are paid by the government ¹. The LURD receives a fixed award from the government (approximately US \$1200), and one year of health insurance. The donor and recipient meet at DATPA before donation to negotiate the amount of supplemental "rewarding gift" (\$2300-\$4500). For recipients without adequate means, DATPA recruits assistance from charitable organizations ¹. Only the Shiraz Transplant Center requires all KT candidates to wait six months for DD KT prior to referring to DATPA for LURD². The ESRD office maintains demographic data on transplantation ³, but lacks centralized data on outcomes. Reports from single centers indicate excellent patient and graft survival rates ^{2,4–6}

Author: Nasrollah Ghahramani, MD, MS, FACP Affiliation: Assistant Professor of Medicine and Public Sciences Division of Nephrology College of Medicine Pennsylvania State University

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Corresponding Author: Dr. Nasrollah Ghahramani, MD, MS, FACP Corresponding Author's Institution: Penn State College Medicine -Hershey Medical Center.

Paid Donation in Iran

Address: Mail Code H040 500 University Drive Hershey, PA, 17033 Telephone: 1-717-531-8156 Fax: 717-531-6776 nghahramani@hmc.psu.edu

Characteristics of donors

Approximately 90% of the LURDs are male, 80% are married, the majority have at least high school education (6.2% post-secondary), and 84% are categorized as poor $^{6-8}$. The mean monthly income is US \$175.0 \pm 68.5 (concurrent national average: \$225), more than 60% live under the poverty line, and 25% are unemployed (national rate: 11.2%) ^{8,9}. Financial factors are the sole motives for donation in approximately 40% of donors 8. In a national study of 500 donors, 95% had experienced at least one stressful life event, most frequently financial hardship, during the 6 months prior to donation ¹⁰. The main financial needs were medical expenses, and debt relief ^{8,9}. The payment had a moderate effect on the donor's finances in 63% of cases ⁹. The QOL scores among LURDs in Iran are lower than the general population ¹⁰. This is in contrast to previous studies that have identified a positive impact of donation on psychological outcomes ^{11,12} and likely reflects the large proportion of LURDs who expect financial gain ¹⁰. While an older study (n=300) found that 85% of donors were dissatisfied with their donation ¹³, two recent larger studies (combined n= 1046) report satisfaction in approximately 90% of the donors ^{8,9}. More than 75% of donors expressed interest in receiving information about outcome of the transplant and the recipient ⁸. There has been concern about coercion of women into donation in the Iranian LURD program. While much of the available data suggest that, worldwide, women are more likely to donate and less likely to receive a kidney, the situation is reverse in Iran. Data from Norway indicate that the majority of LDs are female, while the majority of recipients are male ¹⁴. In the US, women are more likely to donate but less likely to receive a kidney than men ¹⁵. This is true for LRD, LURD and spousal pairs ^{16,17}. In Iran, for LURD KTs, 16% of the donors and 39% of the recipients are female ¹⁸. While this data might suggest a bias against offering transplant to females, it alleviates the concern about exploitation of women as paid donors. A likely explanation for the predominance of male donors in Iran is the incentive that would be more relevant to the male as the traditional head of household responsible for family finances. In summary, the donors tend to be poor young married men, who are financially motivated towards donation. Despite financial motivation, most of them maintain an interest in the outcome of the transplantation and the patient. There is no required organized follow-up of the donors and the vast majority of nephrologists surveyed perceive the one year of insurance to be insufficient for long-term follow-up ¹⁹. A 10-vear pilot study of annual follow-up of 408 donors was launched by the Iranian Academy of Medical Sciences in 2006; first year preliminary results on 90 donors have been reported in abstract form ²⁰.

Impact on deceased donor and living related donor transplantation

A flourishing paid LURD KT program is likely to lead to stagnation of the DD programs and fewer LRD transplants. In Iran, brain death legislation in 2000 allowed DD transplantation; by the end of 2006, 1546 DD organ transplantations (1066 KT) were performed. The number of DD transplants has increased at disappointingly slow pace, with the majority being performed in Shiraz ³. Whereas nationally DD KTs account for 5–10% of the total annual KTs ^{21,22} review of 10-year data from Shiraz shows that from 1355 KTs, 38% were from DDs ⁵. Also, while only 15% of KTs in Iran are from LRDs ²³, 30% of KTs from Shiraz are from LRDs ⁵.

Transplant tourism

Recognizing the potential for commercialization, and in accordance with the Istanbul Declaration, transplantation of foreigners was completely prohibited in April 2010 ²⁴. The largest number of foreigners transplanted in Iran consists of Afghan refugees, who were allowed to receive KT from Afghan donors; they were not allowed to volunteer as donors to

Iranians ¹. Prior to the prohibition, despite scrutiny to avoid transplant tourism, there were reports of foreign nationals receiving KT from Iranian paid donors ^{25,26}. Data from one of the largest programs indicate that approximately 2.5% of the KTs were performed on foreigners (refugees: 1%; Iranian expatriates: 0.9%; others: 0.6%) ²⁷. Citizens from neighboring countries with inadequate or non-existent KT program (mainly Afghanistan and Azerbaijan) have undergone LURD transplantation in Iran without supervision of DATPA. It is suspected that brokers inside Azerbaijan made arrangements for 18 patients from Azerbaijan to receive kidneys from paid Azeri donors in Iran ²⁵. In 2008, the Ministry of Health closed a university transplant unit due to allegations of irregularities ²⁵.

Discussion

The LURD program has succeeded in increasing the number of KTs. Iran has one of the largest numbers of living donor transplantations ²⁸. With an annual ESRD incidence of 57 per million population (pmp) and annual KT rate of 28 pmp, the waiting list is negligible ¹. Despite its success, the system has definite flaws and limitations. The reward is not inflation-adjusted and the recipient bears the major burden of payment ²⁵. In the absence of a required organized follow-up of donors (a major flaw in the model – and a major flaw in transplant programs of many industrialized countries) donor outcomes data are limited. Nephrologists discourage patients from contacting random donors and centers only accept donors referred by DATPA. However, potential donors publically post flyers and the highest bidding patient may contact them prior to meeting in DATPA. The program has moved from serving the needs during a period of turmoil to become the primary form of transplantation. It has shifted from bridging the gap between demand and supply to the most convenient choice for the patient and the government ²¹. The combination of a LURD program and deficiency of national infrastructure for DD transplantation has impeded establishment of the latter. DD transplantation has lagged behind total transplants with no noticeable efforts towards public education about DD and LRD transplantation and the proportion of LRD KTs has progressively declined ²⁹. A goal of the model was to provide transplantation to patients with no LRD. However, 81% of LURD KT recipients have a potential LRD ²⁹. This mentality of "convenience" has overshadowed medical and ethical benefits of LRD KT. The policy of "no questions asked" prior to LURD KT should be replaced by a mandatory waiting period, as required in Shiraz. This has led to a significant increase in DD and LRD transplantations ⁵. **In conclusion**, the pioneers in Iran should be commended for developing a unique model during a period of post-revolution, war and sanctions. In such a setting, the model with proactive supervision and dynamic revisions prevented inevitable rampant commercialization. While Iran was never a significant market, restriction of transplants to Iranians further minimizes chance of transplant tourism. Directed donation and lack of safeguards against mutual exploitation are major flaws. The program in Shiraz, with a mandatory waiting period, and an established DD multi-organ transplant infrastructure addresses some of the pitfalls and should be employed as a model for the rest of the country.

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Paid Donation in the Philippines

Benita Padilla

Key Points

- 1. Paid living donation is not associated with increased donor satisfaction, in most instances the donors would not agree to donation.
- **2.** Paid living donation misaligns the goal of living donation; it becomes money at the expense of safety for the living donor.

Between 2002 and 2008, the Philippine Department of Health administered an organ donation program that allowed prospective kidney providers to sign up, be allocated to prospective recipients and receive a "gratuity package" for their kidney. While the administrative order which created this program specifically stated that "sale and purchase of kidneys is prohibited", the "incentives" offered were so generous that they represented valuable consideration for the average Filipino. These consisted of P100,000 (Philippine peso) for reimbursement of lost income for 4 months, P75,000 for livelihood assistance, P100,000 life insurance, 10-year membership with the government health insurance system and free annual check-up for 10 years. This was at a time when the national average income for the whole family for an entire year was reported to be P172,000.

The government was not equipped to monitor this program closely and was quite unprepared for the consequences. Transplant tourists began to pour in as many desperately poor Filipinos queued to give up a kidney for an imagined chance at a better life. During this period, the number of transplants to foreigners increased by 1200% whereas the number of transplants to Filipinos increased by only 89% (1). This occurred despite a regulation that foreign recipients should not comprise more than 10% of all transplant recipients in every transplant facility.

Two community-based studies have reported on the outcomes of kidney vendors in the Philippines. In 2008, a cluster of kidney vendors was identified in three towns in Quezon province located 220 km southeast of Manila. As of 2011, 198 kidney vendors have been identified and are being given regular follow-up through a joint project of the Philippine Society of Nephrology, non-government organizations and government units. Among these kidney vendors, 73% reported no improvement in their financial status, 74% would not sell a kidney again if given the chance to re-visit their decision and 96% would not recommend

that others sell a kidney. Many reported being transported to Manila by an agent in groups and being instructed to thwart normal screening procedures, such as by taking medication to mask a hypertensive condition or submitting the chest radiographs of another person (2). In another study performed in several communities between 2007 and 2008, 311 kidney vendors were found through snowball sampling. In this population, 36% reported no improvement in their financial status while 41% reported improvement that was fleeting; 80% regretted their decision to sell a kidney. Brokers were involved in 86% of the transactions. Although 69% were advised to seek medical follow-up, only 40% actually did so (3). In both these studies, agents were reported to withhold part of the donor payment until the donor brings in a new recruit.

Since these two studies reported on mostly unregulated commercial transactions, a third study was designed to assess the success of the government incentive program administered through the National Kidney and Transplant Institute. In 2009, an effort was made to determine the status of the 164 individuals who received "gratitudinal gifts" between 2004 and 2007. In contrast to the other studies, this paper reported that 90% of the donors do not regret their decision and 65% said that their financial situation was better one year after donation (4). However, the validity of these findings is seriously hampered by the fact that only 81 donors, or 49% of those who participated in the program, could be interviewed. The effort to find the donors was described to be "aggressive and well-funded" and the fact that less than half of them could be evaluated for the study is testimony to the reality that donor follow-up is still poor even within the government-regulated program.

While the Philippine government was unambiguous in its intention not to allow organ sale, and statements from religious, professional and civic organizations make it clear that the Philippine public is not in favor of transplant commercialism, there was apparently a failure to recognize that the nature and dangers of any valuable consideration given in exchange for an organ does not change regardless of whether it is called a gift, reward, gratuity or incentive. As the accompanying commentary to Principle 5 of the WHO Guiding Principles state, "national law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs (5)."

From 2008 onwards, revisions in the implementing rules and regulations of the Anti Human Trafficking Law, a presidential directive disallowing foreigners to receive organs from Filipino living donors, and new administrative orders from the Department of Health have effectively ended this experiment in "incentivized" kidney donation in the Philippines.

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Preamble for a discussion on paid donation

Paying for kidney or other organ donation has lead to heated debates about donor and recipient welfare. Many have argued that paying for donation leads to coercion and exploitation of the poor and in the end produce more harm than good. Others have said that payment helps the poor and we should all, no matter who, have sovereignty over our bodies and thus are allowed to donate for remuneration. Although world health organizations and governments in many countries have now banned the process of paying for donation, there is still ongoing payment legally and illegally. Thus, this timely set of three papers from Iran, Pakistan and the Philippines where paid donation has been extensively trialed will allow the reader to decide for themselves whether the benefits and/or harms of this practice are now clear.

Key Points

- ☐ The program has led to increasing the number of kidney transplants and diminishing the waiting list.
- ☐ Directed donation and lack of safeguards against mutual exploitation are major flaws.

 Table 1

 Post Nephrectomy complaints and renal function in vendors

Complaint	Kidney Vendors n=104	Control Donors n=184	p.value
Mean age	30.5 ± 8.1	30.6 ± 7.8	0.91
Male: Female	4.5:1	4.2:1	-
Physical Weakness	71 (68.3%)	4 (2.1%)	0.0001
Fatigue	11 (10.5%)	0 (0%)	0.0001
Urinary Tract Symptoms	50 (48.1%)	6 (3.2%)	0.0001
Depression	5 (4.8%)	1 (0.5%)	0.010
Body Mass Index (BMI)	20.02 ± 2.84	23.02 ± 4.27	0.0001
Hypertension	18 (17.3%)	17 (9.2%)	0.04
GFR by Cockcroft-Gault ml/min	70.94 ± 14.2	95.4 ± 20.44	0.0001
Urine Protein/Creatinine Ratio	0.15 ± 0.11	0.10 ± 0.10	0.0001
Deranged Liver Functions	14 (13.4%)	5 (2.7%)	0.0001
Anti HCV Positive	25 (24%)	2 (1.0%)	0.0001

 Table 2

 Comparison of outcome of recipients of vended kidneys with living related donor transplants

Parameters	Recipients of Vended Donors (n=126)	Recipients of Living Related Donors (n=180)	p.value
Acute Rejection %	42 (33%)	31 (17%)	0.005
Creatinine at 1 year mg/dl	1.84 ± 1.28	1.27 ± 0.44	0.0001
Surgical Complication %	28 (22%)	14 (8%)	0.001
Medical Co-morbid %	35 (28%)	14 (8%)	0.0001
Total Deaths	34 (27%)	12 (6.0%)	0.001
Death with Function	13 (10%)	2 (1.0%)	0.001
Graft survival – 1 year	86%	94%	0.0001
– 5 years	45%	80%	0.00001