

# A Revised Iranian Model of Organ Donation as an Answer to the Current Organ Shortage Crisis

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Kidney transplantation has become the treatment of choice for patients with end-stage renal disease. Six decades of success in the field of transplantation have made it possible to save thousands of lives every year. Unfortunately, in recent years success has been overshadowed by an ever-growing shortage of organs. In the United States, there are currently more than 100 000 patients waiting for kidneys. However, the supply of kidneys (combined cadaveric and live donations) has stagnated around 17 000 per year. The ever-widening gap between demand and supply has resulted in an illegal black market and unethical transplant tourism of global proportions. While we believe there is much room to improve the Iranian model of regulated incentivized live kidney donation, with some significant revisions, the Iranian Model could serve as an example for how other countries could make significant strides to lessening their own organ shortage crises.

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A recent brief communication by Fallahzadeh and colleagues and an editorial published in December 2013 issue of the *American Journal of Transplantation* discuss the suboptimal outcomes, such as low quality of life, and the need for provision of better follow-up care for paid live kidney donors.<sup>1,2</sup> Like they, we agree that changes are needed but want to emphasize that the system per se, while flawed, is nonetheless remarkably successful. As a matter of fact, it is our contention that with certain improvements, the Iranian Model—the only system known to have eliminated the kidney waiting list—could serve as an example for other countries.

Fallahzadeh and colleagues acknowledge that their study is limited in providing baseline demographic, educational, socioeconomic, and clinical data for living kidney donors in Shiraz.<sup>1</sup> These data could potentially be useful in identifying problems with the Iranian Model. We agree with the editors that the difference in incidence of microalbuminuria between the paid unrelated and

unpaid related donors is problematic (35% versus zero, respectively). Given the significantly shorter follow-up period for paid versus related donors (2.9 years versus 3.8 years, respectively), there are concerns for the presence of compromised pre-operative donor evaluation when donor payment is allowed.<sup>2</sup> It is possible that had paid kidney donors been followed for the same period of time as related kidney donors, the difference in the incidence of microalbuminuria and other complications could have become even more prominent. This was taken as evidence that the Iranian Model is irreparably flawed.<sup>1,2</sup>

Like Fallahzadeh and colleagues' report,<sup>2</sup> earlier reports from Iran, one by Azar and coworkers and another by Zargooshi, raise legitimate concerns regarding donor long-term safety in at least some transplant centers in Iran.<sup>1,3,4</sup> Zargooshi evaluated 300 paid organ donors who were on average 5 years post donation.<sup>3</sup> He found that 60% to 70% of paid donors reported isolation from society, severe postoperative depression, anxiety, and negative

financial and physical impact after donation. Moreover, 80% were dissatisfied with postoperative physical stamina, and 94% were unwilling to be known as donors. Mental preoccupation with kidney loss was present in 55% of the paid donors and interfered negatively with their life, and 62% reported negative effects on their sense of being useful and productive.<sup>3</sup> The report by Azar and coworkers on 86 kidney transplant donors (93% were paid unrelated donors) showed a postdonation complication rate of 55% during a mean follow-up time of 17 months.<sup>4</sup> Complications in donors included hypertension (37.5%), serious surgical complications (5.8%), kidney failure (serum creatinine  $\geq 1.4$  mg/dL; 6.9%), microalbuminuria (10.4%), microscopic hematuria (13.9%), pyuria (8.1%), persistent pain (44.1%), severe depression (9.3%), urinary calculi (6.9%), and varicocele (24.1% of male donors).<sup>4</sup>

Azar and coworkers and Zargooshi questioned whether with the current condition of organ donation in Iran, the paid living unrelated kidney donation is safe at all. However, the report by Azar and coworkers did not have a control group of living related transplant donors from the same geographic region and transplant center for comparison. It is plausible that they would find similar incidences in their living related donors. Zargooshi relies on old data from a very economically depressed part of Iran (ie, Kermanshah). Many of the donors he interviewed donated before the Iranian government began to regulate unrelated donations. He did not use a standard questionnaire for his interviews. Zargooshi's report also lacks a socioeconomically and demographically matched control group for the prevalence of psychiatric problems. It also lacks such a control for the sense of hopelessness and dissatisfaction with life in such a population, as well as the limited choices of people living in such extreme poverty and facing desperate acute financial predicaments. In a multicenter study on quality of life of the paid donors from Iran, 95% of the respondents reported at least 1 stressful life event during the 6 months prior to organ donation.<sup>5</sup> Given these circumstances, it is impossible to know whether the stress and anxiety felt by the paid donors interviewed by Zargooshi was a preexisting condition or due to the donation.

On the other hand, it should also be noted that there is at least 1 important alternative explanation

for Fallahzadeh and colleagues' findings. It may be presumed that paid kidney donors tend to be less educated and come from a lower socioeconomic class than related donors. The paid donor group in Fallahzadeh colleagues' study was 81% men and averaged 34.2 years old (the related donor group was 35% men and averaged 40.7 years old). Young men in general suffer the financial pressures of having to find a way to support themselves and their families, but as evidenced by several studies, such financial pressures are particularly acute among paid kidney donors.<sup>3,6</sup> Young men struggling to overcome poverty and depression also probably suffer higher rates of infectious diseases (hepatitis, human immunodeficiency virus, etc) and drug addiction that could potentially be the cause of a higher rate of albuminuria in paid donors. Anyone who is in need of money to get out of a financial predicament or who desires money to make a drastic life change regardless of socioeconomic class might want to participate in a paid kidney donation, but it is likely, as in any society, that those in greatest need will be those most likely to turn to compensated donation, and this group will be less healthy in general than the population taken as a whole. Hence, systems of compensated kidney donation that draw donors from populations high in indigency need to take extra precautions in assessing the health of all donors.

But ensuring the health of paid donors may not be the only imperative. While we know of no definitive study on this point, donors desperate to be paid may also be more likely to ignore health risks or lie about factors that might disqualify them from donating (eg, addiction or family coercion). Thus, the current economic crisis in Iran (the result of continued economic sanctions, inflation, and high unemployment) means government and healthcare agencies need to be extra vigilant to ensure informed consent and fair dealings on all sides of the transplant equation. From what we observed in Iran, many regions could do a better job of providing more detailed disclosures regarding risks and benefits for both donors and recipients, and there is a need for both living related and unrelated donors to receive this information earlier in the donor-recipient matching process. This being said, we found that 99% of the recipients we interviewed were glad to have the option of

reducing their waiting time by paying a donor. And a nearly as high percentage, about 90% of the paid donors we interviewed, were also glad that they had the option to donate to help improve their financial situation. The most common regret we heard from paid donors was, not that they had donated, but that they wished they had received a larger payment.<sup>7</sup>

We also found it very interesting that in Fallahzadeh and colleagues' study, a majority of the living related donors were women (65%) of a slightly older age ( $40.7 \pm 9.7$  years), while there was a small percentage of significantly younger women (19%,  $34.2 \pm 7.2$  years) among paid unrelated donors. This raises a concern that there may be undue pressure to have female members of the family donate. These data do not definitively prove that there is such pressure, but the numbers suggest more extensive study is needed and that in the meantime transplant teams should take special precautions to ensure that women are not being coerced into donating.

In contrast to the above reports that raise concerns on the long-term wellbeing of the donors, there are other reports that indicate a high percentage of paid donors do in fact improve either (or both) their immediate or long-term financial situation. Heidary Rouchi and colleagues sent questionnaires to 25 kidney transplant centers in Iran and collected data on 600 paid living unrelated donors. Their report showed that 86.5% of the donors felt complete satisfaction and 11.5% felt relatively satisfied at the time of discharge from hospital.<sup>8</sup> Another similar short-term study of 478 paid live donors from 30 Transplant centers showed that 91% were satisfied shortly after donation.<sup>9</sup> Our own data collected from 6 different transplant regions at the end of 2008 included 44 paid donors who gave us information on their financial wellbeing. Of those, 27% said the donation did not resolve their financial problems, but 73% said their financial problems were resolved. Of those who were financially stable, 39% were interviewed within a year of donation, while 34% were interviewed 1 to 7 years post donation.<sup>7</sup> These seemingly conflicting reports emphasize the need for comprehensive long-term follow-up of paid donors.<sup>10</sup> While the immediate cash provided often seems to alleviate urgent financial needs, more efforts are needed to help ensure long-term benefits.

An important question to keep in mind is what such potential donors will do if deprived of the opportunity to sell a kidney. What could they do instead to alleviate their financial predicament, prevent impending homelessness, help a sick relative, or avoid imprisonment for failure to pay a tort judgment? What other courses of action are available and at what cost to themselves and to the society? If the alternatives were incarceration, loss of a loved one, stealing, murder, suicide, or homelessness, then selling a kidney and saving a life would be a more reasonable and honorable choice, even if the relief is partial or temporary.

Nevertheless, the above reports indicate that the transplant authorities in Iran should develop a more rigorous pretransplant physical and psychological health assessment for their paid donors, provide a more generous financial incentive, institute more extensive healthcare benefits, and find a way to ensure better follow-up data collection. One option that might help further several of these goals is to link follow-up medical checkups to significant payments and the continued renewal of annual health insurance. We also suggest that Iran needs a more comprehensive system of data collection that includes all major transplant centers in the country. Something like the US Organ Procurement and Transplantation Network would be ideal to help ensure accuracy and uniformity in data collection.

Furthermore, while the situation for Iranian patients with kidney disease and their donors is far from ideal, the situation in the United States is worse. The remarkable success of kidney transplantation over the past 6 decades has resulted in an exponential increase in the number of end-stage renal disease patients waiting for a kidney, while the supply of kidneys available for transplant has barely increased, and certainly not increased enough to come close to meeting the current demand. In the United States, by December 2013, over 100 000 patients were actively waiting for a kidney or kidney-pancreas transplant. However, in the past 8 years (2005 to present) the supply of kidneys has been only around 16 500 to 17 000 per year (10 000 to 11 000 deceased and around 6000 live donor kidneys per year), and there has been a steady decline in the annual number of living donor kidneys from a peak of 6647 in 2004 to only 5619 in 2012.<sup>11</sup> Moreover, there has been an annual mortality rate of around 7% among the patients

waiting for a kidney.<sup>11</sup>

The challenges faced in the United States are similar to those found in the rest of the world—the global organ crisis has led to transplant tourism and a black market in kidneys that creates dangerously high risks for everyone involved. Rich patients with kidney disease from the United States, Canada, Europe, Japan, Australia, Israel, Saudi Arabia, and Oman travel to countries like China, the Philippines, Pakistan, India, Brazil, Bolivia, Iraq, Moldova, Peru, Turkey, and Colombia, and pay black market brokers tens to hundreds of thousands of dollars to buy kidneys.<sup>12</sup> These kidneys are obtained from executed prisoners (in case of China around 90% of kidneys are from executed prisoners) or illegally obtained from desperately poor locals, with no guarantee that they will be informed of the medical or legal risks they are taking. The nephrectomies and transplants are often performed under unsafe or questionable hospital conditions and by poorly qualified medical or surgical teams, without proper donor and recipient evaluation before surgery. Under such circumstances, recipients are at risk of getting suboptimal organs, transferable diseases such as hepatitis B, hepatitis C, or human immunodeficiency virus, and run a high risk that organ traffickers will cheat them. There is even a chance that they will be prosecuted for illegal activity once they return to their home country.

Donors run even higher risks. Some studies show that donors are frequently cheated by organ brokers who do not pay donors the money promised.<sup>6</sup> Furthermore, donors on the black market frequently go without adequate postoperative care. Black market donors are additionally vulnerable because they lack any form of legal remedy if cheated or mistreated because they themselves run the risk of being arrested for having participated in an illegal activity.<sup>12</sup>

The Iranian Model has evolved over the past 30 years and provides an example of a nation willing to take a novel, daring approach to solving its kidney shortage. The result of the Iranian Model has not always been positive, but to its credit, the Iranian medical community has responded by continually adjusting the system to deal with problems as they arose—banning organ sales to foreigners, demanding more government benefits for both donors and recipients, and providing ever more comprehensive guidelines for the donor

vetting process.<sup>13</sup> Health authorities in Iran should continue to improve the system by alleviating the shortcomings of its program and through more vigilant enforcement of existing laws, regulations, and guidelines. The system is clearly in need of better predonation evaluation and long-term follow-up of donors, as well as more social support networks for donors, life-long health insurance, and more financial compensation for donors.

Nevertheless, the Iranian Model has achieved several important milestones that other nations should learn from. Most significant are that Iran has:

- (1) created a legal structure for enforceable donor-recipient contracts;
- (2) provided guidelines to help ensure informed consent for donors and their next of kin (although we feel disclosure should be more comprehensive and provided earlier in the donation process);
- (3) licensed nongovernmental organizations to provide free assistance to both recipients and donors in brokering transplant deals and applying for related government and charitable benefits (Gordon and Gill in their editorial erroneously call the oversight provided by nongovernmental organizations “putative oversight.” It was our observation that in most instances the oversight was comprehensive, involving several levels of psychological, social, and medical evaluations.);
- (4) promulgated regulations that require the same citizenship between donors and recipients (This prevents transplant tourism and protects Iran’s own kidney disease patients from being excluded in favor of potentially higher paying foreigners.);
- (5) initiated important data collection and studies to evaluate its system of paid donation such as those done by Fallahzadeh and colleagues, Zargooshi, and others (Although we feel much more needs to be done and a more comprehensive and standardized national data collection system needs to be created.);
- (6) funded through the national government all transplant related medical care, at least for citizens, albeit not for resident aliens;
- (7) required that transplantations be performed at university hospitals and by qualified transplant teams; and
- (8) abolished the waiting list and consequently

the mortality of the patients awaiting for a transplant that is a major achievement which deserves special recognition.

As a result of all these achievements, unlike anywhere else in the world, everyone who medically qualifies for a transplant in Iran can begin the process for getting one, and in some regions of the country there is even a waiting list for people who want to donate.<sup>7,11,13</sup>

A frequently cited criticism of the Iranian model of incentivized kidney donation is that it will result in abandonment of the deceased donor transplant program. This is a valid concern, but not a criticism that can be justly levied against Iran. There are 2 main reasons why historically cadaver transplants were uncommon in Iran. The first is that Iran lacked the medical infrastructure to develop such a system. The second is that there were cultural and perceived religious objections to using deceased donors that needed to be overcome before a system of cadaver organ donation could be implemented.

In June 2000, the Iranian parliament passed the Organ Transplantation Brain Death Act. The Act legalized deceased organ donation. In 2002, the Iranian Network for Transplant Organ Procurement was created. As a result of these laws, there has been a steady rise in the number of cadaveric kidney transplantations in Iran. During the year 2000, of a total of 1421 kidney transplants, 86% were living unrelated and only 2.2% (0.4 per million population) were of cadaveric donors. These numbers have changed to 2285 transplants in 2010 when only 69% were living unrelated and 26% (7.9 per million population) were of cadaveric donors. Thus, both absolute and relative numbers of deceased donor transplants have increased in Iran over the past decade.<sup>13</sup>

We anticipate that the number of deceased donor organ transplants will continue to increase; particularly as current and past impediments to such development are overcome. Iran is working on correcting its infrastructure deficiencies, inadequate public awareness of deceased organ donation and the option of a free cadaver organ transplant, medical attitudes about the necessity for (and advantages of) deceased organ donation, poor understanding of the concept of brain death both among physicians and the general public,

public misconceptions of the religious laws (despite the religious permission [Fatwa or Islamic Edict] of Ayatollah Khomeini in 1989), and cultural barriers (evidenced by the two-third refusal rate of brain dead families in the early reports).<sup>13,14</sup> In a recent study, Mahdavi-Mazdeh and colleagues reported that the rate of family refusal for organ donation in the eligible dead brain donors has significantly decreased in both Tehran (20% refusal rate) and other cities (50% refusal rate), which have brought the overall refusal rate to 25% across the country.<sup>15</sup> As authors have discussed, this huge improvement seems to be the result of continuous public education and increased awareness of the families as well as the expertise of the transplant coordinator teams.<sup>15</sup>

These significant impediments make it clear that the availability of living paid donors has had little, if any, direct effect on the availability of deceased organ donation in Iran. In the year 2013, 40% of the kidney transplantations performed in Iran were from a cadaveric source. There has also been increasing support and approval of deceased organ donation between Iranian population, scholars and teachers (responsible for next generation education).<sup>16</sup>

The cadaveric organ donation as it currently exists in Iran is “purely altruistic” with the one exception that in some cases funeral expenses are covered for the deceased.<sup>14</sup> It is interesting that Fallahzadeh’s article, which relies on data collected in Shiraz, fails to mention that in Shiraz, and nowhere else in Iran, recipients are technically prohibited from paying donors.<sup>7</sup> When we were there in 2008, both donors and recipients were required to sign a statement that no money would be exchanged beyond the funds provided by the national government, and this payment was to be understood purely as reimbursement for donation related expenses and not a payment per se.<sup>7</sup> Also in Shiraz, unlike elsewhere in Iran, all recipients are required to find an altruistic (unpaid) related donor or wait at least 6 months for a cadaver kidney, while on maintenance dialysis, before even initiating the search for an unrelated donor.<sup>7</sup>

The Iranian model of a government incentivized paid kidney donation program was initiated in 1987-88 when the Department of Health and Medical Education first budgeted funds for donor payments (a government reward of ten million Iranian Rials equivalent of US \$ 3000 to US \$ 6000

buying power in 2008). Payment, 1 year of health insurance, and exemption from military service for donors became official government policy in 1995 when the Iranian parliament created a Center for Special Diseases to administer these donor benefits on the national level.<sup>17</sup> The model was initially intended to create a government-funded, tightly regulated, and well-compensated paid donor renal transplantation program. Initially, the donor and recipient were not supposed to have any direct financial relationship. Failure of the government to increase the financial incentives with inflation put the burden on recipients to make up the shortfall. In the current Iranian model, donors and recipients are in direct contact with each other and the amount of legally enforceable “financial reward” is negotiated with the help of a not-for-profit, charity organization (Iranian Kidney Foundation), which also supervises donor-recipient matches. This system has eliminated paid kidney brokers by replacing them with nongovernmental organizations run by volunteers. Unfortunately, it has left in place the donor-recipient bargaining, which we found in our study of 211 donor-recipient interactions was what caused both donors and recipients the most stress.<sup>7</sup>

The direct financial relationship between the potential donor and recipient should be avoided by either changing the current scheme to a fully government-compensated system, or alternatively by creating an organ bank run by state health authorities or the Iranian Kidney Foundation. Another option is to make anonymity the status quo but to allow, like in open adoption, personal contact between donors and recipients only when both parties wish to know each other. Paid donors should not be allowed to choose their recipient. This decision should be completely at the discretion of the transplant team or health authorities based on the health condition of the recipients and compatibility of the donors (through a similar scoring or priority system as the one used by United Network for Organ Sharing or other organ sharing systems).

Providing lifelong health insurance to the donors and support of the media in creating a more positive social image for them could help in increasing the long-term donor’s satisfaction. Linking the follow-up medical checkups to significant payments and the continued renewal of annual health insurance

could also help in donors follow up and protecting their long-term health condition. Increase in satisfaction along with a better health support and more social respect should help to reduce the postdonation psychological stress. No alternatives or independent method for obtaining organs other than altruistic donations from family members should be allowed. In many western countries including the United States where the authors of this article are currently practicing, there are laws and regulations which prohibit organ selling. Even in the current system, there is no law or regulation to prevent governments creating incentive systems, even financial, for the donors including free lifelong health insurance for self and the family (as suggested and supported in this article). Once such modifications are implemented there is a chance that the Iranian Model could become an example for other countries, but not before.

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#### CONFLICT OF INTEREST

None declared.

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