

Ethical problems in *ex vivo* or cadaver organ transplantation: should the donation be paid?



Ann. Ital. Chir., 2015 86: 187-191
pii: S0003469X15023544
www.annitalchir.com

Paolo Bruzzone

Assistant Professor of Surgery. Department of General Surgery, Surgical Sciences and Transplantation "P. Stefanini", "Sapienza" University of Rome, Rome, Italy

Ethical problem in *ex vivo* or cadaver organ transplantation: should it donation be paid?

Financial incentives for organ donation (from living or cadaveric donors) have been considered ethically acceptable by some bioethicists, and recently, according to the media, by Prof. Gary Becker, Nobel Laureate for Economy. However, the only countries to have approved a law allowing financial incentives for organ donation are Iran in 1988 and, in some way and much later, Singapore and Saudi Arabia. In Europe financial incentives for donors are prohibited, except maybe in Austria. In Germany, it is forbidden to purchase organs not only in the home country, but all over the world. The author was involved, as peer reviewer of a major international Transplant journal, in the evaluation of some papers concerning paid kidney living donors in Iran, and therefore made an extensive literature search on this topic and more generally on paid kidney living donation all over the world. The situation in Italy will also be reported and analysed.

KEY WORDS: Living kidney donor, Organ commercialism, Regulated market, Transplantation, Related, Unrelated

Financial incentives for organ donation (from living or cadaveric donors) have been considered ethically acceptable by some bioethicists, and recently, according to the media, by Prof. Gary Becker, Nobel Laureate for Economy.

However, the only countries to have approved a law allowing financial incentives for organ donation are Iran^{1,2} in 1988 and, in some way and much later, Singapore and Saudi Arabia³. In Europe financial incentives for donors are prohibited, except maybe in Austria. In Germany, it is forbidden to purchase organs not only in the home country, but all over the world.

The author was involved, as peer reviewer of a major international Transplant journal, in the evaluation of some papers concerning paid kidney living donors in Iran, and therefore made an extensive literature search on this topic and more generally on paid kidney living donation all over the world. The situation in Italy will also be reported and analysed.

Although in Iran the first living donor kidney transplantation was performed in 1967, only after the approval of the "Organ Transplantation and Brain Death Act" in 2000 deceased donor kidney transplant could be performed. In the meanwhile, a government regulated and funded unrelated living kidney donation program was introduced, with a reported significantly reduction of waiting list. According to this program, if a patient does not have a living related kidney donor (LRKD) and do not want to be on a deceased donor waiting list, is referred to a non-profit organization run by patients with chronic renal diseases, named Iranian Patients' Kidney Foundation (IPKF), which matches patients with paid unrelated kidney donors (PUKD). Iranian government covers all the fees for kidney transplantation and immunosuppressive drugs, and provides to PUKD a

Pervenuto in Redazione Novembre 2014. Accettato per la pubblicazione Gennaio 2015.

Correspondence to: Paolo Bruzzone, MD, FACS. Via Santa Maria Goretti 38/10,00199 Rome, Italy. (E-mail: bruzzonepaolo@alice.it.)

reward equivalent to 400 US dollars and only 1 year of free medical insurance. The actual payment corresponding to the equivalent of 4000 US dollars to the PUKD is done directly by the kidney transplant recipient, in some cases with the help of nongovernmental charitable organizations. PUKD are poor young men (or women) who after donation have, if compared to LRKD, lower than normal Quality of Life (QOL) scores and a higher percentage of microalbuminuria (35% vs. 0%, $p < 0.001$)⁴; all of them after “donation” remained poor, some have been rejected from society or even from family, or divorced.

In the author's home country, Italy, cadaveric and living organ donation started almost simultaneously, as a brain dead law was timely approved. Paid organ donation has never been tolerated, because since the earlier law (Legge 26 giugno 1967, n.458. G.U. n. 160 27 giugno 1967. Edizione straordinaria) concerning living kidney donation, which is still effective, the donor has to be evaluated by a psychiatrist/psychologist and has to confirm to a judge that he/she did not receive any coercion or economic incentives to donate; punishment for organ brokers is also included in this law⁵. The punishment is severe (2 to 5 years of jail and perpetual exclusion from the medical or health profession) also in case of commercialism of organs from a deceased donor, according to the current Italian law (Legge 01 aprile 1999, n.91. G.U. Serie Generale, n. 87 del 15 aprile 1999)⁶. These rules have been obviously accepted by the Transplant Regulatory Authority, Centro Nazionale Trapianti (C.N.T.), which has issued guidelines (“Documento Informativo sul programma di trapianto di rene da donatore vivente”) for living kidney donation⁷, including a consent form to be signed by the donor, confirming his/her free willingness to donate, without coercion or money incentives. Donors' data (including strict follow-up controls) are kept in a Registry maintained by C.N.T. since 2001. The only financial benefit for the donor is the immediate exemption from “ticket”, which is a modest money contribution required for medical examinations, medical tests and drugs from the Italian National Health System (Sistema Sanitario Nazionale S.S.N.). According to data published by the informative system of C.N.T.⁸, in 2013 2836 transplants from cadaveric donors as well as 243 transplants (liver and kidney) from living donors have been performed: similar numbers have been reported also in the previous years. It is the personal opinion of this author that living donation in Italy unlikely would be significantly increased if a new transplant law would allow financial incentives or even paid organ donation. A recently published paper written by Indian authors⁹ seems to confirm that the proposed introduction of incentives for organ donation¹⁰, even only within a strictly controlled trial, is not the right approach to help to start deceased donor transplant programs, in order to improve organ shortage, to reduce waiting list time and to fight organ trafficking and commercialism.

As far as the Iranian model is concerned, although other Iranian authors have questioned the clinical significance of microalbuminuria in PUKD^{11,12}, direct payment by the recipient, lack of long-term follow-up of the donor and possible poor donor evaluation are evident weak points of this system, which should be changed^{13,14}, particularly before proposing it in Western countries.

Fallahzadeh's study, as other papers from Iran, includes only a small and selected study sample.

Microalbuminuria after nephrectomy in paid donors implies that the clinical evaluation of these donors have been less than scrupulous: data before nephrectomy have not been provided, but the short interval since donation suggests that microalbuminuria was probably present prior to nephrectomy. It is also possible that proteinuria has developed postoperatively due to poverty in the paid donors, as it happened in India¹⁵. Furthermore, few paid unrelated donors in Iran undergo follow-up care due to insufficient financial support, and donors are not appropriately informed about living donor complications or the need for lifelong follow-up care¹⁶. The Iranian Model does not meet most of the proposed standards for a regulated system of organ sales¹⁷, including nondirected donations, provisions to ensure long-term donor follow-up, and access to health care; the lack of public reporting as well as of transparency prevented its acceptance to solve organ shortage internationally, and raised some doubts about the integrity of the program.

Some transplant professionals, including Prof. Francis L. Delmonico¹⁸, have proposed “ethical incentives” such as the payment of funeral in case of cadaveric donor, or other benefits for the living donor, but not detraction such a “tax credits”, that are instead insistently proposed by other transplant professionals, and by “bipartisan” politicians, to the American Congress.

Italian public opinion seems strongly against paid organ donation, according to its reaction to papers published in newspapers or magazines, books, movies, or Television broadcasts, involving cases of organ commercialism in Eastern Europe, Middle East or Far East. In Poland a written questionnaire was offered to students, concluding that “most young people are not willing to be paid donors, but they want to help disinterestedly”¹⁹; a similar study was performed in Germany²⁰, and another one in Switzerland²¹. It is the author's knowledge that this kind of research has never been done in Italy in general public, or in physicians as well as transplant professionals, as it has been done in other countries^{22,23}. Only a semistructured anonymous questionnaire was proposed to Italian fourth year medical school students attending a seminar within the nephrology course: most students were contrary to organ commercialism²⁴. In conclusion, there are very few objective data concerning the Italians' opinion on paid organ donation. According to a note dated September 22, 2014 on the website of the Transplantation Society²⁵: “The Custodian Group

of the Declaration of Istanbul (DICG) required Mayor Marino (the Mayor is a transplant surgeon himself....) to arrange a private audience with Pope Francis with the intention of deriving the support of Pope Francis for the principles of Declaration Of Istanbul (DOI) and the mission of DICG....". Among other informations presented to Pope Francis: "Six years ago (2008), professionals from all over the world came to Istanbul to write the Declaration Of Istanbul, to combat organ trafficking and transplant tourism and commercialism....In the United States (US), there is a movement to enable cash payments/benefits/college tuitions/tax credits/retirement benefits as a way of enticing the young to be compensated for their organs. DICG opposes that direction and needs support of Pope Francis to ensure that the US Congress will not amend the law prohibiting organ commercialism. Financial incentives are to be distinguished from removing financial disincentives and rendering the donor at a monetary loss...." . Three recommendations have been proposed as a result of this audience: "Retain the prohibition against financial gain for organ donation, including in the United States.....Support the recently adopted Council of Europe Convention against organ trafficking. Call for deceased organ donation by all cultures throughout the world". Finally, as result of this meeting: "DICG has been invited to submit a background/reference document that Pope Francis will use in a pronouncement to be widely reported in 2015". Prof. Marino, who, besides being Mayor of Rome, is a politician from the main Left Party in Italy, Partito Democratico (P.D.), also said to journalists: "The Pope did not mince his words. He has authorized us to say publicly that we need to encourage the donation of organs out of compassion, but the trade in organs is immoral and a crime against humanity". As reported by Adnkronos press agency, Mayor Marino also added: "Jail should be provided not only for people trafficking organs, but also for those who receive the organs, taking advantage from other people's need". He had previously written: "Punishment should be provided also for physicians taking care of transplant patients in their home country.....pretending to ignore how and where the illegal transplant has taken place...." ²⁶

According to the aforementioned "Council of Europe Convention against Trafficking in Human Organs" ²⁷: Article 4-Illicit removal of human organs.

1) Each party shall take the necessary legislative and other measures to establish as a **criminal offence under its domestic law**, when committed intentionally, the removal of human organs from living or deceased donors:

- a) where the removal is performed without the free, informed and specific consent of the living or deceased donor or, in the case of the deceased donor, without the removal being authorized under the domestic law;
- b) where, in exchange for the removal of organs, the living donor or a third party, has been offered or has received a **financial gain or comparable advantage**;

c) where, in exchange for the removal of organs from a deceased donor, a third party has been offered or has received a **financial gain or comparable advantage**.

2) Any State or the European Union may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, by a declaration addressed to the Secretary General of the Council of Europe, declare that it reserves the right not to apply paragraph 1.a of this article to the removal of human organs from living donors, in exceptional cases and in accordance with appropriate safeguards or consent provision under its domestic law. Any reservation made under this paragraph shall contain a brief statement of the relevant domestic law.

3) The expression "**financial gain or comparable advantage**" shall, for the purpose of paragraph 1.b and c, not include compensation for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations, or compensation in case of damage which is not inherent to the removal of organs.".

According to the Committee of Ministers of the Council of Europe: "Spain has been chosen to host the opening ceremony of the signing of the Council of Europe Convention against Trafficking in Human Organs. The event will take place in Santiago de Compostela on 24 and 25 march 2015" ²⁸. Probably Italy and many other countries will sign this Convention; therefore it will be difficult to perform trials of "regulated market" in Europe, maybe within Eurotransplant, as vaguely suggested by Matas ^{29,30}.

Actually, there has been only one criminal trial in Italy for organ commercialism, and all the prosecuted physicians have been completely acquitted by the judges. However, particularly in the past, Italian patients may have performed "transplant tourism" and traveled abroad to be transplanted by paid donors ³¹.

Indeed, it is quite obvious that even in case of a "regulated market", it would be only the poor to sell to the rich. In example, presently an enormous amount of refugees escape from Africa to Europe through Italy, and could be easily tempted to sell non-vital organs. In Nancy Scheper-Hughes' opinion, this already happens in Africa in order to pay for the travel ³² to Europe: such a practice, by the way, exposes the recipients to the potential transmission of Ebola virus. At least in the United States of America(USA), End Stage Renal Disease(ESRD) is higher in Black and Hispanic donors ³³, and theoretically one could identify genetic predispositions, such as APOL1 gene mutations, precluding kidney donation ³⁴. "Regulated market" would not destroy organ commercialism, as it still would be faster ³⁵ and easier to get an organ illegally rather than undergoing the complex rules of a legally regulated procedure.

The Italian Authorities are wisely worried about the risk of organ commercialism: when recently both Comitato

Nazionale di Bioetica (C.N.B.)³⁶ and Consiglio Superiore di Sanità (C.S.S.)³⁷ authorized “Good Samaritan” donation, required strict anonymity to make impossible any contact between donor and recipient, and therefore to be sure that donation is really free. Such as for all cases of living donation, the evaluation of both donor and recipient has to be performed by a “third party” and a prioritization of the living donor in the cadaveric kidney waiting list is advised, in case he/she should need a kidney transplant due to renal failure occurring after kidney donation. No Good Samaritan donation has still occurred in Italy.

In conclusion, due to the opposition of Public Opinion, Health and Religious Authorities as well as of the Government and “bipartisan” politicians, it seems highly improbable that a law allowing organ “regulated market”, such the Iranian one, would be approved in Italy, or even in Europe, at least in the next future.

Riassunto

Incentivi economici per la donazione d'organo (vivente o cadavere) sono stati considerati eticamente accettabili da parte di alcuni bioeticisti e, recentemente, secondo i media, dal Prof. Gary Becker, Premio Nobel per l'economia. Tuttavia le uniche Nazioni che hanno approvato una legge che permetta incentivi economici diretti per la donazione d'organo sono l'Iran nel 1988 e, in modo relativamente simile e molto più tardi, Singapore e l'Arabia Saudita. In Europa simili incentivi per i donatori di organo sono proibiti, con la sola parziale eccezione, forse, dell'Austria. In Germania è proibito acquistare organi non solo nel paese nativo, ma anche nel resto del mondo. L'Autore è stato coinvolto, in qualità di “peer reviewer” di una prestigiosa rivista trapiantologica internazionale, nella recensione di alcuni manoscritti sulla donazione da vivente a pagamento in Iran, e ha pertanto effettuato una accurata revisione della bibliografia su questo argomento e più in generale sulla donazione di organi a pagamento in tutto il mondo. La situazione in Italia verrà inoltre riportata e analizzata.

References

- Ghods AJ, Savaj S: *Iranian model of paid and regulated living-unrelated kidney donation*. Clin J Am Soc Nephrol, 2006; 1:1136-145.
- Mahdavi-Mazdek M: *The iranian model of living renal transplantation*. Kidney Int, 2012; 82:627-34.
- Al Sebabel M, Alenazi AM, Sabbagh R, et al.: *Donor organ shortage crisis: A Case study review of a financial incentive-based system*. Transplant Proc, 2014; 46(6):2030-35.
- Fallahzadeh MK, Jafari L, Roozbeh J, et al.: *Comparison of health status and quality of life of related versus paid unrelated living kidney donors*. Am J Transplant, 2013; 13:3210-214.
- Legge 26 giugno 1967, n. 458. G.U. n. 160 del 27 giugno 1967. Edizione straordinaria.
- Legge 01 aprile 1999, n.91. G.U. Serie Generale, n. 87 del 15 aprile 1999.
- Documento informativo sul programma di trapianto di rene da donatore vivente. Available at: http://www.trapianti.salute.gov.it/imgs/C_17_publicazioni_1186_allegato.pdf. Accessed October 3, 2014.
- Sistema Informativo Trapianti Available at : <https://trapianti.sanita.it/statistiche>. Accessed October 3, 2014.
- Abraham G, Reddy YN, Amarlopavanathan J, et al.: *How deceased donor transplantation is impacting a decline in commercial transplantation. The Tamil Nadu experience*. Transplantation, 2012; 93(8):757-60.
- Ambagtsheer FA, Weimar W: *A criminological perspective: Why prohibition of organ trade is not effective and how the declaration of Istanbul can move forward*. Am J Transplant, 2012; 12:571-75.
- Einollahi B: *Is proteinuria a common finding after kidney donation?* Am J Transplant, 2014; 14:1224-225.
- Khatami SM, Mahdavi-Mazdeh M: *Perfect is the enemy of good: The Iranian system of paid donation*. Am J Transplant, 2014; 14:1222-223.
- Gordon EJ, Gill JS: *Where there is smoke there is fire: The Iranian system of paid donation*. Am J Transplant, 2013; 13:3063-64.
- Gordon EJ, Gill JS: *Reply (invited response to 2 letters re Iran Editorial)*. Am J Transplant, 2014; 14:1226.
- Sahay M, Narayen G, Anuradha: *Risk of live kidney donation. Indian Perspectives*. J Assoc Physicians India, 2007; 55:267-70.
- Zargooshi J: *Quality of Life of Iranian kidney “donors”*. J Urol, 2011; 166:1790-799.
- Matas AJ, Hippen B, Satel S: *In defense of a regulated system of compensation for living donation*. Curr Opin Organ Transplant, 2008; 13:379-85.
- Delmonico FL, Arnold R, Scheper-Hughes N, et al.: *Ethical incentives. Not payment-for organ donation*. N Engl J Med, 2002; 346:2002-2005.
- Milaniak I, Przybylowski P, Wilczek Ruzyczka E, et al.: *The opinions of young people on paid organ donation*. Organs, Tissues and Cells, 2012; 15:32-38.
- Inthorn J, Wohlke S, Schnidt F and Schicktanz S: *Impact of gender and professional education on attitudes towards financial incentives for organ donation: Results of a survey among 755 students of medicine and economics in Germany*. BMC Medical Ethics, 2014; 15:56.
- Bosisio F, Santiago M, Benarovo L: *Financial incentives to improve organ donation: What is the opinion of the Vaud french-speaking population?* Swiss Med Wkly, 2011; 141:w 13312 doi. 10.4414/sm.w.2011.13312.
- Ghahramani N, Karpavar Z, Shahrouz S: *International survey of nephrologists' perceptions and attitudes about rewards and compensation for kidney donation*. Nephrol Dial Transplant, 2013; 28:1610-621.
- Tong A, Chapman JR, Wong G, Craig JC: *Perspectives of transplant physicians and surgeons on reimbursement, compensation and incentives for living kidney donors*. Am J Kidney Dis, 2014; 64(4):622-32.

24. Piccoli GB, Putaggio S, Soragna G, et al.: *Kidney vending: Opinions of the medical school students on this controversial issue*. *Transplant Proc*, 2004; 36:446-47.
25. Transplantation Society: Available at: <https://www.tts.org/> Accessed October 3, 2014.
26. Marino I: in Mondadori G: *Pezzi di ricambio*. Milano: Giangiacomo Feltrinelli Real Cinema, 2010.
27. Council of Europe: *Convention against Trafficking in Human Organs*: Ministers' Deputies Committee of Ministers Documents CM(2013)79 final 9 July 2014.
28. La Moncloa: *Downloaded from www.declarationofistanbul.org. Accessed October 7, 2014*.
29. Matas AJ, Gaston RS: *The high cost of organ commercialism*. Letter to the editor. *Kidney International*, 2014; 86:855-60.
30. Danovitch GM: *The high cost of organ transplant commercialism*. *Kidney International*, 2014; 85:248-50.
31. Porciani F: *Traffico d'organi. Nuovi cannibali, vecchie miserie*. Milano: Francoangeli, 2012.
32. www.ANSA.it. Accessed on October 10, 2014.
33. Muzaale AD, Massie AB, Wang MC, et al.: *Risk of end-stage renal disease following kidney donation*. *JAMA*, 2014; 311(6):579-86.
34. Allegretti AS, Yeung MY, Riella LV: *Counseling potential donors to the risk of esrd after kidney donation: Glass half-full or half-empty?* *Am J Transplant*, 2014; 14:2434-435.
35. Filippini F: *Santi o schiavi?* Milano: Dalai Editore, 2010.
36. Comitato Nazionale per la Bioetica: *La donazione dal vivo del rene a persone sconosciute (c.d. donazione samaritana)*. 23 April 2010. Available at: www.governo.it/bioetica/pareri_abstract/donazione_rene.pdf. Accessed October 3, 2014.
37. Parere del Consiglio Superiore Sanità - 4 maggio 2010. *Parere in merito a Casi di donatore "samaritano" di rene parere_css_040510 - pdf*, 45 Kb. Available at: <http://www.trapianti.salute.gov.it/cnt/cntLineeGuida.jsp?id=35&area=cnt-generale&menu=menuPrincipale¬menu=normativa&label=norm>. Accessed October 3, 2014.

READ-ONLY COPY
PRINTING PROHIBITED