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Trafficking in Human Organs and Human Trafficking for Organ Removal: A Healthcare Perspective

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1. Introduction

Data from the World Health Organization (WHO) Global Observatory on Donation and Transplantation reveal that almost 120,000 solid organ transplants were performed throughout the world in 2014.[1] However, transplant activity is unevenly spread across different countries, mainly as a result of differences in deceased donation rates. In 2015, only 14 European countries and the US reached more than 20 deceased organ donors *per* million population (pmp), and only 4 European countries registered more than 30 donors pmp. In Latin America, the average was 8.3 donors pmp, and in some other areas the rates were even lower.[2]

Despite the increasing transplant activity throughout the world, it is estimated that it barely covers 10% of the global needs. In 2015, a total number of 30,974 organ transplants were performed in the US, but more than 100,000 people remained on the transplant waiting list.[3] During that same year, 32,707 organ

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1 WHO, Global Observatory on Donation and transplantation: archives of organ reports 2014, available at: www.transplant-observatory.org/data-reports-2014/, accessed 31 January 2017.
2 Council of Europe, *Newsletter Transplant* 2016, available at: www.transplant-observatory.org, accessed 31 January 2017.
3 Organ Procurement Transplant Network database, available at: optn.transplant.hrsa.gov/data/view-data-reports/, accessed 31 January 2017.

transplants were performed in the European Union while 56,504 patients were waiting for an organ.[4]

The gap between demand and supply of organs for transplantation results in patients enduring poor quality of life or, in the worst case, dying while still on the waiting list. This situation leads some desperate patients to consider paying large amounts of money to obtain the organ they need. Huge illegal profits made by unscrupulous criminal networks from illicit organ transplants have led to the emergence of trafficking in human organs (THO) and human trafficking for the purpose of organ removal (HTOR). These practices violate fundamental human rights, endanger individual and public health and tarnish the magnificence of transplantation.

Broadly speaking, THO involves the illegal removal of human organs from living or deceased persons, and any subsequent use of those organs, where a) the removal is performed without the free, informed and specific consent of the living donor, or, in the case of the deceased donor, without the removal being authorised under domestic law; or b) where, in exchange for the removal of organs, the living donor or a third party receives a financial gain or comparable advantage.[5,6] HTOR is a particularly heinous crime as it always involves living persons and victims are forced to give up an organ through the use of fraudulent or coercive means or through the abuse of their desperate financial position.[7,8,9] The true dimensions of both types of transplant-related crimes remain unknown, but the WHO estimates that 5-10% of global transplant procedures result from some form of commercial transaction.[10]

Concerned by the increasing demand of organs for transplantation and emerging unethical practices in the field, the WHO has called on countries to

4 See n. 2.

5 Council of Europe Convention against Trafficking in Human Organs, available at: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216, accessed 31 January 2017.

6 M. López-Fraga et al., 'A Needed Convention against Trafficking in Human Organs', *Lancet* 383, no. 9936 (2014): 2187-2189.

7 Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime, available at: treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XVIII-12-a&chapter=18&clang=_en, accessed 31 January 2017.

8 Council of Europe Convention on Action against Trafficking in Human Beings, available at: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/197, accessed 31 January 2017.

9 Directive 2011/36/EU of the European Parliament and of the Council of 5 April 2011 on preventing and combating trafficking in human beings and protecting its victims, and replacing Council Framework Decision 2002/629/JHA, available at: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:101:0001:0011:EN:PDF, accessed 31 January 2017.

10 Y. Shimazono, 'The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information', *Bulletin of the World Health Organization* 85 (2007): 955-962.

pursue self-sufficiency in transplantation.[11] Self-sufficiency requires the commitment of national governments to cover the transplantation needs of their patients by using resources within their patient population.[12] Actions are required to decrease the prevalence of diseases that can lead to organ failure and subsequently to the need for an organ transplant, and to increase the availability of organs, particularly from deceased donors. The goal of self-sufficiency in transplantation is central to preventing transplant-related crimes in the long-term. Meanwhile, the world is confronted with this difficult ongoing reality.

This article describes the dimension and the forms of THO and HTOR, provides an overview of the stakeholders and consequences of these criminal activities, and discusses the necessary response of healthcare authorities and professionals in preventing and combatting these practices.

2. Current Practices in Transplant-Related Crimes

2.1. Forms of Trafficking in Human Organs and Human Trafficking for Organ Removal

Although THO and HTOR may happen within a given jurisdiction, they very often have a transnational scope and occur as 'transplant tourism'. The term 'transplant tourism', is used to describe a form of travel for transplantation (movement of donors, recipients or transplant professionals across jurisdictional borders) that involves THO or HTOR, or where the diversion of resources (may be organs, professionals and/or transplant centres) to facilitate transplants to foreign patients undermines the country's ability to provide transplant services for its own population.[13]

Based on the movement of donors/victims and recipients across jurisdictions, Shimazono[14] described different forms of transplant tourism (Figure 1):

- Mode 1: the recipient travels to the donor/victim's country.
- Mode 2: the donor/victim travels to the recipient's country.
- Mode 3: the donor/victim and the recipient travel together to a third country.
- Mode 4: the donor/victim and the recipient travel separately to a third country.

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11 World Health Assembly, Fifty-seventh World Health Assembly resolutions and decisions: WHA 57.18: human organ and tissue transplantation, available at: apps.who.int/gb/archive/pdf_files/WHA57/A57_18-en.pdf, accessed 31 January 2017.

12 The Madrid Resolution on Organ Donation and Transplantation, *Transplantation* 91 (2011): S29-S31.

13 Steering Committee of the Istanbul Summit, Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul, *Lancet* 372, no. 9632 (2008): 5-6.

14 See n. 10.

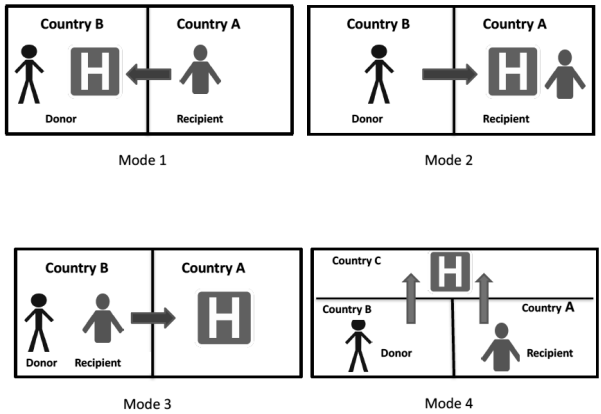

Figure 1. *Modes of international organ trade and organ trafficking. Modified from Yosuke Shimazono- WHO 2nd Global Consultation on Transplantation 28-30 March 2007 Geneva.*

Mode 1, initially described during the 1980s, has been the most frequent form of transplant tourism. A prospective transplant recipient travels to a country where the laws against the sale or purchase of human organs are marred by loopholes or poorly enforced. The organs most readily available in such countries for foreigners are kidneys from paid, living, unrelated 'donors', often victims of exploitation and coercion. Executed prisoners have also been the source of organs for transplant tourists in China, a practice widely condemned by the international community.[15, 16,17] Transplant tourists come from countries in Western Europe and the Middle East, Australia, Canada, Japan, South Korea and the United States. Transplant procedures take place in Central and South America and Eastern Europe, China, Egypt, India, Iraq, Pakistan and the Philippines, among others.[18]

The transnational scope of these practices makes them particularly difficult to identify and prosecute.

15 F. Delmonico et al., 'Open letter to Xi Jinping, President of the People's Republic of China: China's Fight against Corruption in Organ Transplantation, *Transplantation* 97, no. 8 (2014): 795-796.

16 K.C. Allison et al., 'Historical Development and Current Status of Organ Procurement from Death-row Prisoners in China, *BMC Medical Ethics* 16, no. 1 (2015): 85.

17 T. Trey et al., 'Transplant Medicine in China: Need for Transparency and International Scrutiny Remains', *American Journal of Transplantation* 16, no. 11 (2016): 3115-3120.

18 See n. 10.

2.2. Actors

THO and HTOR involve several actors. The interactions between the different actors are intricate and may vary in different countries and criminal schemes, with certain individuals occasionally having multiple roles. Based on available sources, key actors are described below.

2.2.1. Recipients

Some patients, unwilling to accept the lack of access to transplantation or prolonged times on the waiting list, seek a solution in the form of illegitimate transplantation – locally or in countries with weak or poorly enforced legal frameworks prohibiting THO and HTOR.

Patients looking to purchase an organ may be put into contact with brokers through intermediaries operating in hospital premises or elsewhere. They may have heard about solutions of this nature from friends, fellow patients, family members or dedicated websites.[19] Patients may not use a broker and directly arrange a contact with the donor/victim.[20] Occasionally, patients purchase transplant 'package deals' including travel and accommodation expenses, payments to the donor/victim and the broker, and coverage of the medical procedure.

2.2.2. Donor/Victims

Donor/victims of THO and HTOR are usually young males (except in India, where the female gender is predominant[21]) in a critical economic situation or vulnerable position. They believe that selling an organ is the last resort to alleviate, even if temporarily, their extreme poverty.[22]

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19 A. Bagheri & F.L. Delmonico, 'Global Initiatives to Tackle Organ Trafficking and Transplant Tourism', *Medicine Health Care and Philosophy* 16 (2013): 887.

20 F. Ambagtsheer et al., 'Organ Recipients Who Paid for Kidney Transplantations Abroad: A Report', (2014) (HOTT Project) hottproject.com/userfiles/Reports/2ndReportHOTTproject-OrganRecipientsWhoPaidForKidneyTransplantsAbroad.pdf, accessed 31 January 2017; V.R. Muraleedharan, S. Jan & S.R. Prasad, 'The Trade in Human Organs in Tamil Nadu: The Anatomy of Regulatory Failure', *Health Economics, Policy and Law* 1 (2006): 41.

21 D.A. Budiani-Saberi & K.A. Karim, 'The Social Determinants of Organ Trafficking: A Reflection of Social Inequity', *Social Medicine* 4 (2009): 48; N. Scheper-Hughes, 'Keeping an Eye on the Global Traffic in Human Organs', *Lancet* 361, no. 9369 (2003): 1645.

22 A. Tong et al., 'The Experiences of Commercial Kidney Donors: Thematic Synthesis of Qualitative Research', *Transplant International* 25 (2012): 1138.

Illegal networks offer them money or coerce them to be donors. It has also been reported that donors have been confined or kidnapped and subject to involuntary nephrectomy before being allowed to return home.[23, 24]

2.2.3. Local Recruiters, Brokers and Facilitators

Usually the local recruiter is the person who tries to identify victims in the area where he/she lives or in the same country, as he/she knows the potential victims, speaks the same language and is familiar with their society and their different circumstances.[25] Sometimes a donor/victim becomes a local recruiter, voluntarily or forced, to convince a person to donate an organ. This explains the presence of clusters of people taking part in this activity in small communities in some countries, such as India or the Philippines.[26]

Brokers, coordinators or intermediaries are those who are in charge of connecting donors/victims and recipients (maybe using a local recruiter) and facilitating commercial transplantations in healthcare premises: organising travel and accommodation for both the donor/victim and the recipient, arranging payments, identifying all healthcare professionals needed (nurses, surgeons, anaesthetists, etc.), contracting translators if necessary, contacting insurance companies, forging legal documentation, etc.[27] They are the coordinators of the logistics required for this kind of procedure.

2.2.4. Healthcare Professionals

Without the direct or indirect participation of healthcare professionals, THO and HTOR could not take place. The most obvious participants include nephrologists/hepatologists, transplant surgeons and anaesthetists who evaluate donors/victims and recipients and carry out the transplant procedures. Other participants may include nurses and other professionals to assist the

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23 A.A. Aronowitz, *Human Trafficking, Human Misery: The Global Trade in Human Beings* (Westport: Greenwood Publishing Group 2009); C. Paddock, 'Philippine Government Bans Organ' www.medicalnewstoday.com/articles/105980.php, accessed 31 January 2017.

24 United Nations Office on Drugs and Crime, Report of the Secretary-General to the Commission on Crime Prevention and Criminal Justice, on Preventing, Combating and Punishing Trafficking in Human Organs, E/CN 15/2006/10, 21 February 2006.

25 OSCE (Organization for Security and Co-operation in Europe). Office of the Special Representative and Co-ordinator for Combating Trafficking in Human Beings. Trafficking in Human beings for the purpose of organ removal in the OSCE region: analysis and findings. 8 July 2013.

26 B. Padilla, G.M. Danovitch & J. Lavee, 'Impact of Legal Measures Prevent Transplant Tourism: The Interrelated Experience of the Philippines and Israel', *Medicine Health Care and Philosophy* 16, no. 4 (2013): 915.

27 United Nations Office on Drugs and Crime, Assessment Toolkit: Trafficking in Persons for the Purpose of Organ Removal (2015), available at: www.unodc.org/documents/human-trafficking/2015/UNODC_Assessment_Toolkit_TIP_for_the_Purpose_of_Organ_Removal.pdf, accessed 31 January 2017.

surgical team and provide post-operative care, and laboratory and technical staff to perform ancillary medical tests.

Healthcare professionals may knowingly participate in THO and HTOR. Although not recruiting donors/victims or recipients themselves, they may undertake the necessary clinical procedures while being aware of their illegitimate nature. They may also participate by intentionally ignoring – for a variety of reasons – well-established international standards that aim to avoid the exploitation of the poor and vulnerable. In addition, healthcare professionals may face situations where both the donor/victim and the recipient present themselves for evaluation at a transplant centre simulating a legitimate relationship and an altruistic motivation for living donation. This may prove difficult for healthcare professionals to detect, particularly in the absence of appropriate safeguards in the evaluation and authorisation of the living donation procedure.

3. Consequences of Organ Trafficking

Normative living kidney donation and transplantation, based on international standards for the evaluation and selection of donors and recipients, are considered safe medical procedures.[28, 29] This does not, however, exclude the possibility, as for any other medical activity, of serious risks both during or after the surgical procedure, which requires comprehensive information to ensure informed consent and guarantee long-term follow-up.[30, 31] The perioperative mortality of living kidney donors reported in the literature is 0.02-0.03%. The incidence of major complications, such as a surgical re-intervention, may reach 1%.[32, 33, 34] In the long term, survival of kidney donors is similar to that of the general population.[35, 36] However, living kidney donation seems to

28 The Ethics Committee of the Transplantation Society, The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor, *Transplantation* 78, no. 4 (2004): 491-492.

29 T.L. Pruett et al., 'The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor', *Transplantation* 81, no. 10 (2006): 1386-1387.

30 J. Weitz et al., 'Living-Donor Kidney Transplantation: Risks of the Donor-Benefits of the Recipient', *Clin Transplant* 17, suppl. 20 (2006): 13-16.

31 H. Wolters & T. Vowinkel, 'Risks in Life after Living Kidney Donation', *Nephrol Dial Transplant* 27, no. 8 (2012): 3021-3023.

32 D. Segev et al., 'Perioperative Mortality and Long-term Survival Following Live Kidney Donation', *JAMA* 303, no. 10 (2010): 959-966.

33 A.J. Matas et al., 'Morbidity and Mortality after Living Kidney Donation, 1999-2001: Survey of United States Transplant Centers', *American Journal of Transplantation* 3 (2003): 830-834.

34 A.J. Ghods, 'Renal Transplantation in Iran', *Nephrol Dial Transplantation* 17 (2002): 222-228.

35 H.N. Ibrahim et al., 'Long-term Consequences of Kidney Donation', *The New England Journal of Medicine* 360, no. 5 (2009): 459-469.

36 C. Fournier et al., 'Very Long-term Follow-up of Living Kidney Donors', *Transplant International* 25 (2012): 385-390.

have an impact on survival in a significant manner (increasing all-cause and cardiovascular mortality) when a selected control group in a comparable state of health to a donor is used as a reference. This association is stronger after ten years of the donation procedure, which reinforces the need to maintain strict medical follow-up in the long run.[37, 38]

3.1. Consequences for Donors/Victims

The frequency of the above-mentioned risks associated with living kidney donation increases in the context of THO and HTOR. The absence of strict donor selection criteria means that up to 30% of commercial donors may not be medically suitable living donors.[39] In transplant-tourism situations, open nephrectomy recovery is more frequent and it increases immediate post-operative complications such as pain and the need for re-intervention, delaying the reincorporation of the donors to their normal activity (for extended periods, if not permanently).[40, 41, 42]

Inadequate screening and the absence of long-term follow-up of donors/victims lead to an increased risk of impaired renal function, proteinuria at significant levels and development of chronic renal failure.[43]

There are also negative psychosocial consequences: a high percentage of donors/victims are stigmatised, isolated and humiliated in their communities.[44] In addition, the payment they receive is usually less than the promised amount and does not significantly change their financial situation. Occasionally, treatment for medical complications deriving from the donation needs to be carried

37 G. Mjøen et al., 'Long-term Risks for Kidney Donors', *Kidney International* 86 (2014): 162-167.
38 A. Garg et al., 'Cardiovascular Disease in Kidney Donors: Matched Cohort Study', *BMJ* 344 (2012): e1203.
39 N. Ghahramani, S.A. Rizvi & B. Padilla, 'Paid Donation: A Global View: Outcomes of Paid Donation in Iran, Pakistan and Philippines', *Advances in Chronic Kidney Diseases* 262 (2012): 19.
40 S.A. Naqvi et al., 'Health Status and Renal Function Evaluation of Kidney Vendors: A Report from Pakistan', *American Journal of Transplantation* 8, no. 7 (2008): 1444-1450.
41 T. Nanidis et al., 'Laparoscopic Versus Open Live Donor Nephrectomy in Renal Transplantation: A Metanalysis', *Annals of Surgery* 247 (2008): 58-70.
42 D. Budiani-Saberi & A. Mostafa, 'Care for Commercial Living Donors: The Experience of an NGO's Outreach in Egypt', *Transplant International* 24 (2011): 317-323.
43 A.X. Garg et al., Proteinuria and Reduced Kidney Function in Living Kidney Donors: A Systematic Review, Meta-Analysis, and Meta-Regression', *Kidney International* 70, no. 10 (2006): 1801-1810.
44 F. Moazam, R.M. Zaman & A.M. Jafarey, 'Conversations with Kidney Vendors in Pakistan', *The Hastings Center Report* 39, no. 3 (2009): 29-44.

out without proper healthcare support, which may further increase the donor's situation of indebtedness.[45, 46, 47]

3.2. Consequences for Recipients

The results of transplantation performed under THO and HTOR are inferior to those of transplants performed under legitimate circumstances, as reflected in the medical literature.[48,49, 50] Causes are diverse. Donor screening for infections, malignancies or other transmissible diseases may not be appropriate. There is frequently an inadequate selection of recipients, with transplants being undertaken in patients with co-morbidities or surgical risks, who would not have been considered suitable for transplantation in their home country. There is also a poor matching between donors/victims and recipients that may increase the risk of acute rejection. Flawed transplant procedures and poor perioperative care further increase the risk of illegitimate transplantation. Moreover, the follow-up of transplant tourists upon their return to their home country is compromised due to non-existent or incomplete medical records, which hampers the appropriate transfer of care.

Up to one-third of recipients of illegitimate organs require hospital admission upon return to their home country and within the first three months after transplantation, and they frequently need surgical re-interventions.[51, 52, 53] Graft and patient survival after illicit transplantation are significantly lower than with legitimate transplantation procedures, regardless of the characteristics of recipients.[54, 55]

Recipients of illicitly obtained organs exhibit a higher risk of post-transplant infectious and malignant complications. The rate of infection is 45-54% *versus*

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45 See n. 39.

46 S.A. Naqvi et al., 'A Socioeconomic Survey of Kidney Vendors in Pakistan', *Transplant International* 20 (2007): 934-939.

47 M. Goyal et al., 'Economic and Health Consequences of Selling a Kidney in India', *JAMA* 288, no. 13 (2002): 1589-1593.

48 I. Sajjad et al., 'Commercialization of Kidney Transplants: A Systematic Review of Outcomes in Recipients and Donors', *American Journal of Nephrology* 28, no. 5 (2008): 744-754.

49 R.M. Merion et al., 'Transplants in Foreign Countries among Patients Removed from the US Transplant Waiting List', *American Journal of Transplantation* 8, no. 2 (2008): 988-996.

50 C. Hsu et al., 'Outcomes of Overseas Kidney Transplantation in Chronic Haemodialysis Patients in Taiwan', *Nephrology* 16 (2011): 341-348.

51 See n. 49.

52 A. Vathsala, 'Outcomes for Kidney Transplants at the National University Health System: Comparison with Overseas Transplants', *Clinical Transplants* (2010), 149-160.

53 M.Ş. Sever et al., 'Outcome of Living Unrelated (Commercial) Renal Transplantation', *Kidney International* 60, no. 4 (2001): 1477-1483.

54 See n. 47.

55 J.M. Babik & P. Chin-Hong, 'Transplant Tourism: Understanding the Risks', *Current Infectious Disease Reports* 17 (2015): 473.

5% in patients who receive an organ in legitimate circumstances. Infections include those derived from the surgical procedure itself (for example, wound infections), nosocomial, opportunistic and donor-derived infections. They may be caused by a geographically restricted pathogen acquired as a donor-derived infection or in the peri-transplant period while staying in an endemic area[56] or by multidrug-resistant microorganisms. Transplant tourism increases the risk of several viral infections, most importantly those caused by HIV, HBV, and cytomegalovirus, which has been reported in up to 33% of patients returning from transplantation abroad.[57, 58, 59] An increased risk of malignancy and related mortality has been observed among transplant tourists, most likely caused by a deficient donor and recipient selection and inappropriate post-transplant follow-up.[60, 61]

3.3. Consequences for the Healthcare System

THO and HTOR have negative consequences for the healthcare system of countries involved, since they generate public and professional mistrust in altruistic donation and transplantation programmes. This may decrease a society's commitment to organ donation, reducing deceased donation rates and hindering progress to self-sufficiency in transplantation.[62, 63, 64]

Transplant tourists returning home frequently require care which is more complex than what is required after normative transplantation. It increases the burden of their healthcare system and public health threats. Some of the imported infections, such as those caused by multidrug-resistant microorganisms, pose substantial risks not only to individual patients, but also to their communities.

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56 A.E. Anker & T.H. Feeley, 'Estimating the Risks of Acquiring a Kidney Abroad: A Meta-Analysis of Complications Following Participation in Transplant Tourism', *Clinical Transplantation* 26, no. 3 (2012): E232-E241.

57 See n. 47.

58 L.H. Chen & M.E. Wilson, 'The Globalization of Healthcare: Implications of Medical Tourism for the Infectious Disease Clinician', *Clinical Infectious Diseases* 57, no. 12 (2013): 1752-1759.

59 A. Odedra, S.T. Green & R. Bazaz, 'United Kingdom and Republic of Ireland Renal Physicians' Experiences of Patients Undergoing Renal Transplants Abroad: A Questionnaire-based Cross-sectional Survey', *Travel Medicine and Infectious Disease* 12, no. 4 (2014): 702-706.

60 M.K. Tsai et al., 'De Novo Malignancy Is Associated With Renal Transplant Tourism', *Kidney International* 79, no. (2011): 908-913.

61 M.C. Chung et al., 'Increased Risk of Post-transplant Malignancy and Mortality in Transplant Tourists: A Nationwide Population-based Cohort Study in Taiwan', *Medicine* (Baltimore) 93, no. 29 (2014): e344.

62 R. Matesanz, 'Organ Donation, Transplantation, and Mass Media', *Transplantation Proceedings* 35 (2003): 987.

63 C.J. Rudge et al., 'International Practices of Organ Donation', *British Journal of Anaesthesia* 108, Suppl. 1 (2012): 48-155.

64 F.L. Delmonico et al., 'A Call for Government Accountability to Achieve National Self-sufficiency in Organ Donation and Transplantation, *Lancet* 378, no. 9800 (2011): 1414-1418.

4. Response of the Healthcare Community

In view of the growing problems of organ sales and exploitative actions against the impoverished and vulnerable in the context of the global shortage of organs, the healthcare community has issued standards of practice for transplant professionals and a variety of recommendations for governments and healthcare authorities. These standards and recommendations invoke principles that are essential in preventing and combatting illegitimate activities in the recovery and clinical use of human organs. They are also unequivocally aligned with principles promoted by the Council of Europe Convention of Human Rights and Biomedicine[65] [more specifically by its Additional Protocol concerning transplantation of organs and tissues of human origin[66]] and the European Union through recent Directives that are legally binding for the twenty-eight Member States of the European Union.[67,68]

4.1. World Health Organization

The World Health Assembly adopted a new version of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation in 2010 (Table 1, at the end of this article).[69, 70] Although not legally binding, these principles have profoundly influenced national legislation and professional codes of practice.

From the perspective of THO and HTOR, the WHO Guiding Principles can be classified into two groups:

– Several principles promote practices that prevent the exploitation of the disadvantaged and the unethical obtaining or clinical use of organs from deceased persons. Guiding Principles (GP) 1 and 2 specify the conditions under which organs for therapeutic use may be obtained from persons

65 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, available at: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164, accessed 31 January 2017.

66 Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, available at: www.coe.int/en/web/conventions/full-list/-/conventions/treaty/186, accessed 31 January 2017.

67 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, available at: eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32010L0053, accessed 31 January 2017.

68 Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for Transplantation, available at: ec.europa.eu/health//sites/health/files/blood_tissues_organs/docs/organs_impl_directive_2012_en.pdf, accessed 31 January 2017.

69 World Health Assembly, Resolution WHA63.22, 21 May 2010.

70 WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, available at: www.who.int/transplantation/en/, accessed 31 January 2017.

who have been declared dead. GP 3 puts emphasis on the need to increase the number of donations from the deceased to decrease the burden imposed upon donors, and limits the conditions for living organ donation. GP 4 expands on additional guarantees to protect minors and incompetents from exploitation. GP 10 and 11 make reference to aspects that are intended to ensure the quality and safety of human material for clinical use but can also contribute to preventing transplant-related crimes – for example, by ensuring traceability (the capacity for an organ to be traced from donor to recipient and vice versa) and by means such as scrutiny of facilities engaged in organ procurement and transplantation.

– Other principles encourage practices that can directly combat THO and HTOR. GP5 is a core principle in this regard, since it defines and prohibits organ commercialisation. The violation of the principle that the human body or its parts shall not give rise to financial gain is deemed of such severity that it represents the essence of THO as defined and criminalised by the Council of Europe Convention against Trafficking in Human Organs.[71] GP 6 further specifies that any advertisement about the need for, or the offering of, substances of human origin with a view to financial gain must equally be forbidden. GP 8 limits professional fees for participating in procurement and transplantation activities to amounts that are justifiable. GP 7 elaborates on the responsibility of healthcare professionals to verify that organs to be clinically used have been obtained through legitimate means and clearly states that healthcare providers should never reimburse the costs of transplants that have been performed in breach of the WHO principles.

4.2. International Professional Associations

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (DOI) was created at an international summit convened by The Transplantation Society (TTS) and the International Society of Nephrology (ISN) in Istanbul (Turkey) in April 30 and May 1, 2008.[72] The summit included 158 participants from almost 80 countries representing scientific and medical bodies, government officials, social scientists, and ethicists.

The DOI represents a professional statement that calls on countries to prohibit organ trafficking and transplant tourism. Professionals at the summit also opposed organ commercialisation because it targets impoverished and vulnerable

71 See n. 5.

72 Steering Committee of the Istanbul Summit, Organ trafficking and transplant tourism and commercialism: the Declaration of Istanbul, *Lancet* 372, no. 9632 (2008): 5-6.

donors and inexorably leads to inequity and injustice. The key ethical principles promulgated by the DOI are summarised in Table 2 (at the end of this article).

The responsibility of the relevant international societies in the fight against organ trafficking has also been reflected through the creation of the Declaration of Istanbul Custodian Group (DICG) in 2010, by TTS and ISN (www.declarationfistambul.org). The DICG represents a platform of professionals devoted to promoting, implementing and upholding the principles of the DOI. Organised as a network, the DICG directly combats organ trafficking, transplant tourism and commercialism, and encourages the adoption of effective and ethical transplantation practices around the world.

5. The Key Role of Healthcare Professionals and Authorities in Combatting Organ Trafficking and Transplant Tourism

A distinctive feature of THO and HTOR compared to other criminal activities is that both require the involvement of healthcare professionals and facilities in several steps of the criminal offences. However, the necessary involvement of healthcare professionals and facilities, both before and after the transplant procedure, also provides a unique opportunity to help prevent, detect and combat these crimes. Through appropriate responses to the different legal and ethical tensions that may appear when facing situations that may lead to or follow illicit transplantation procedures, healthcare professionals and authorities can play an essential part in the multifaceted approach to effectively preventing and combatting transplant-related crimes.

5.1. Pre-transplantation Phase

In their daily practice, nephrologists and other transplant professionals face patients who may consider travelling abroad to purchase an organ. Numerous studies have suggested that patients discuss their medical tourism plans with their physicians.[73, 74] This may include questions about transplant options and the appropriateness and safety of illegitimate transplant procedures.

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73 J. Snyder et al.: '"Do Your Homework... and then Hope for the Best": The Challenges that Medical Tourism Poses to Canadian Family Physicians' Support of Patients' Informed Decision-making', *BMC Medical Ethics* 14 (2013): 37-46.

74 R. Johnston et al., 'Canadian Family Doctors' Roles and Responsibilities toward Outbound Medical Tourists "Our True Role Is... within the Confines of Our System"', *Canadian Family Physician* 59, no. 12 (2013): 1314-1319.

Healthcare professionals who turn a blind eye to these intentions and even support their patients in the search for facilities and providers of such services are complicit in the commission of a criminal offence. They are also doing a great disservice to their patients by not informing them of the gruesome realities and consequences of these practices, not only for the donor/victims, but for themselves.

Healthcare professionals should provide information to the patient about the legal and ethical issues associated with the purchase of an organ and health risks. While they may not feel they owe a legal duty to the individual providing the organ, disclosure of the relevant ethical issues, social and medical harms for the organ donor would allow the patient to better understand and evaluate whether he/she wants to go ahead. Moreover, as members of the medical community, all healthcare professionals have responsibilities to society and the health of others, as recognised in professional codes of practice.

In addition, the desperation of recipients may mislead them about the prospects of a successful surgery arranged through illicit means, and the risks they will be taking. Therefore, it is essential that all relevant healthcare professionals have the necessary knowledge to provide patients with all the relevant information. Resources should be made available that provide clinicians with a summary of the facts and ethical concerns about THO and HTOR most relevant to this phase of the physician/patient interaction. For example, the DICG has developed a patient brochure in several languages to warn patients (and their physicians) of the risks entailed in undergoing a commercial transplantation.[75]

When, for any reason, legitimate travel for transplantation is the option of choice for a given patient, this should always be done within the framework of cooperation agreements between countries, in authorised centres in the country of destination and in accordance with the highest ethical and medical standards. Prior to travel, healthcare authorities in both countries should pre-approve the procedure and the transplantation teams on both sides should liaise to ensure appropriate transfer of care before and after the transplantation procedure. If, in spite of all the information provided, a patient has decided to purchase an organ, healthcare professionals must continue to act in the best interest of their patients, including carrying out appropriate investigations and prescribing medications that are necessary for the current clinical management. In addition, in most jurisdictions, patients retain the right to access and obtain a copy of their medical record,[76] even if the physician knows the information will be used

75 Brochure 'Thinking about buying a kidney? STOP', available at: www.declarationofistanbul.org/resources/patient-brochure-thinking-about-a-kidney, accessed 31 January 2017.

76 Canadian Medical Protective Association, 'Releasing a Patient's Personal Health Information: What Are the Obligations of the Physician?', 2012, available at: www.cmpa-acpm.ca/duties-and-responsibilities/-/asset_publisher/bFaUiyQG069N/content/releasing-a-patient-s-personal-health-information-what-are-the-obligations-of-the-physician-;jsessionid=B65C4670035A2DA471BBC6938C53B0CD, accessed 31 January 2017.

for the purchase of an organ. However, healthcare professionals should never take any actions that would facilitate an illicit transplant, such as providing letters for the team performing the transplant or performing additional tests to facilitate transplantation. On the contrary, it seems appropriate for healthcare professionals to remind patients that their choice may seriously hamper the continuity of care both at destination clinics and once they return home, with the potential subsequent clinical challenges for the patient.

Another circumstance in which healthcare professionals play a major role in preventing transplant-related crimes within their home country is in the appropriate evaluation of donor-recipient pairs. This evaluation should ensure the medical suitability and safety of the procedure for both donor and recipient as well as the legitimacy and motivations of potential donors.

The non-resident donor is particularly vulnerable, and assessing the validity of their consent to donation – which must be free, specific and informed – can be especially challenging. The donor/victim, in exchange for some form of financial inducement to give consent, may have been given inadequate or insufficient information about the donation procedure, risks and potential consequences. They may have been subject to coercion to agree to donation. The donor may be falsely presented as having a genetic or emotional relationship with the recipient. Another reason why non-resident living donors may be especially vulnerable is that they may be given poor or no post-operative care and follow-up once they return to their home country.

Healthcare professionals in charge of the donor-recipient evaluation should be particularly vigilant for any 'red flags' indicative of HTOR and THO. These include: memorised, or mechanically recited stories; fearful demeanour in the potential donor; inability to produce identification documents or having suspicious documents which raise doubts on the relationship between donor and recipient; documents in the possession of an accompanying party; donor and recipient not speaking the same language; travelling from a country where the requested transplant service is provided, etc.

On account of all these risks, relevant authorities must put in place appropriate legislation and measures to ensure lawful practice and good donor care, with sufficient safeguards to ensure trafficking scenarios are promptly effectively detected and reported to the authorities.

5.2. Post-transplantation Phase

Both the sophisticated care required for monitoring organ function following transplantation and for the treatment of post-operative complications and the need for lifelong immunosuppression in recipients inevitably bring healthcare professionals into contact with patients who have received an illicitly obtained organ. In these circumstances, professionals and authorities are faced with a number of health, legal, and ethical problems.

In alignment with the recommendations issued by the Canadian Society of Nephrology, there seems to be a broad consensus that, when a transplant recipient returns home to receive post-operative care, healthcare professionals have a duty of care to their patients.[77] This is particularly true in the context of emergent care. However, in situations that do not require urgent attention, individual physicians may elect to defer the care of these patients to another physician.

Considering that specific knowledge and expertise are required to evaluate and care for patients who have received an organ transplant abroad, particularly in circumstances consistent with transplant tourism, these patients should be promptly referred for evaluation at a transplant centre. Professionals at transplant centres should be provided with specific guidelines and training for the screening and evaluation of transplant travellers.

It is nowadays well accepted that countries with solid-organ transplantation systems should establish transplant registries with information on all transplants performed in the country, ensuring transparency, guaranteeing traceability of organs, and allowing for the appropriate follow-up of living donors and recipients using national transplant registries. The DICG has recently proposed that transplant recipients returning home to receive post-transplant care should also be recorded in national transplant registries by their treating physician. In addition, good practice would require that systems of international co-operation between authorities be established to assist in the timely communication of information about patients who have received transplants abroad.

The collection of information on patients transplanted abroad, in particular those having participated in transplant-related crimes, would allow better understanding of the phenomenon of transplant tourism and building of concerted efforts to combat these practices. Therefore, the aggregated data collected by national health authorities should be shared internationally on a regular basis using existing international registries and data collection exercises, in particular, the Council of Europe Newsletter Transplant (www.edqm.eu/en/organ-transplantation-reports-73.html) and the WHO Global Observatory on Organ Donation and Transplantation (www.transplant-observatory.org).

When it comes to the specific cases of travel for transplantation that may involve criminal activity, healthcare professionals and authorities should receive guidance and training to assist them in the identification of such cases. They should become familiar with possible indicators of illegitimate travel for transplantation. Importantly, when identifying potential cases of transplant tourism through these indicators, healthcare professionals will also be able to provide better care to these patients through personalised evaluation and

77 J.S. Gill et al., 'Policy Statement of the Canadian Society of Transplantation and Canadian Society Nephrology on Organ Trafficking and Transplantation', *Transplantation* 90, no. 8 (2010): 817-820.

management, informed by the known risks associated with illicit transplantation procedures.

More controversial is the issue whether healthcare professionals can disclose to a third party, such as law enforcement authorities, that a patient has purchased an illicitly procured organ. Confidentiality principles in the medical field impose some ethical and sometimes legal dilemmas for professionals suspecting that illicit practices have taken place. However, in order to effectively combat transplant-related crimes and prevent established criminal rings from committing further crimes, it is of the utmost importance that countries establish clear and ethical frameworks and develop mechanisms to allow, or even mandate, health professionals and/or health authorities to communicate information about these cases to national law enforcement agencies, according to their national legislations governing patient privacy and confidentiality. This could mean drafting a legislation that provides for a (voluntary or mandatory) non-anonymised reporting of detected or suspicious cases to law enforcement agencies by health professionals or healthcare authorities, even without the patient's consent. Another approach might be the (voluntary or mandatory) reporting of anonymised data that reveals information on entities, hospitals or professionals engaged in illegitimate transplantation but not the identity of the patient concerned. In any event, patients who have received a transplant abroad as part of a transplant-related crime should be encouraged to report their case on a voluntary basis and to assist and co-operate with law enforcement agencies during criminal investigations, provided they are suitably protected.

6. Final Remarks and Conclusions

HTOR and THO are crimes of a global dimension, which result from the desperation of patients in need of an organ transplant and from extreme inequities in the distribution of wealth and access to healthcare in the world.

Greater awareness among all stakeholders is needed to prevent and combat these practices, and protect their victims. Healthcare professionals play an essential role because of their involvement before and after the transplant procedure.

In their daily practice, healthcare professionals may face patients who are considering the option of obtaining an organ through illegitimate means. Professionals should discourage these patients from engaging in such activities and warn them of the potential medical, ethical and legal consequences of their choice. Healthcare professionals should guarantee a careful evaluation and selection of donor-recipient pairs for all living donation procedures. Finally, appropriate frameworks should be created for healthcare professionals to report suspicious or confirmed illicit activities to the relevant authorities, provided that victims are effectively protected.

Table 1. WHO Guiding Principles on the transplantation of human organs, tissues and cells

GP 1	Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if: (a) any consent required by law is obtained, and (b) there is no reason to believe that the deceased person objected to such removal.
GP 2	Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.
GP 3	Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients. Living donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organised, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.
GP 4	No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.
GP 5	Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned. The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

GP 6 Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation.
Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

GP 7 Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

GP 8 All healthcare facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

GP 9 The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.

GP 10 High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.
The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimised on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

GP 11 The organisation and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

Table 2. Key principles of the Declaration of Istanbul on Organ Trafficking and Transplant Tourism

Programmes for screening, prevention and treatment of organ failure should be developed and implemented by local governments.
Recovery of organs from deceased and living donors and transplantation should be legislated for by local governments according to international standards, and requires oversight and accountability by health authorities.
Allocation should be equitable and fair.
Medical care to promote health of both recipients and living donors should be provided in the short and long term.
Self-sufficiency in transplantation should be strived for by jurisdictions, countries and regions.
Organ trafficking, transplant tourism & commercialism should be prohibited to protect impoverished and vulnerable donors and prevent inequity and injustice.