INTERNATIONAL CONFERENCE, MINSK, 6 APRIL 2018

TEN YEARS OF LIVER TRANSPLANTATION IN THE REPUBLIC OF BELARUS: ETHICAL CHALLENGES AND PERSPECTIVES

"CONTRIBUTION OF THE CD-P-TO TO THE FIGHT AGAINST ORGAN TRAFFICKING"

ANA M. PIRES SILVA
LEGAL ADVISOR OF THE DIRECTIVE BOARD/PORTUGUESE INSTITUTE OF BLOOD AND TRANSPLANTATION
NATIONAL FOCAL POINT ON TRANSPLANT-RELATED CRIMES, PORTUGAL

The overall aim of the CD-P-TO (European Committee on Organ Transplantation) is to promote: (a) the non-commercialisation of organ donation, (b) the fight against organ trafficking, (c) the self-sufficiency in transplantation, (d) the equality in access to organ transplantation, (e) the development of ethical, quality and safety standards in the field of donation and transplantation, (f) the transfer of knowledge and expertise between Member States and organisations.

To develop its important mission the CD-P-TO is supported by internationally-recognised experts from Council of Europe Member States, observer countries, the European Commission, the World Health Organization (WHO), representatives from the Committee on Bioethics of the Council of Europe (DH-BIO) and several non-governmental organisations.

Since its creation, the CD-P-TO activity has had a high and direct impact in Member States legislation, organization and professional practices. For instance, the *Guide to the Quality and Safety of Organs for Transplantation* and the *Guide to the Quality and Safety of Tissues and Cells for Human Application*[1], which contains exhaustive guidelines to provide professionals with a useful overview of the most recent developments in the field, to ensure high level of quality and safety standards.

CD-P-TO also plays an important and strong role in the promotion and implementation of several Council of Europe Recommendations in the field of donation and transplantation, as well as international treaties, in particularly, the Convention on Human Rights and Biomedicine[2] – based on the principle of prohibition of financial gain with respect to the human body and its parts -, its Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin[3] -

explicitly prohibits organ trafficking -, and, more recently, the new Convention against Trafficking in Human Organs[4].

Indeed, one of the CD-P-TO major commitments is the fight against transplant related crimes – trafficking in human organs and trafficking in persons for the purpose of organ removal.

Organ transplantation is one of the greatest medical success stories of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. However, organ shortage is the main obstacle in transplantation medicine.The demand for human organs exceeds the availability. Only in Europe, in 2015, eighteen patients died every day while waiting to be transplanted, and 5 new patients were added every hour to a waiting list for transplantation[5].

There are great differences in deceased organ donation rates in the worldwide and wide disparities in the access to and use of transplantation between all continents. Asia, the largest continent on earth, with 60% of the world's population, has only 2-3 % of world's deceased donors. Not all patients in need have access to transplantation. In some countries kidney transplantation is even non-existent or only depends on living donation. Countries with no transplant programs or not well established programs have more risk of organ-exporting where organs from local donors are regularly transplanted to foreigners through sale and purchase.

The shortage of available organs for transplantation and unequal access to transplantation have stimulated the emergence of trafficking in persons for the purpose of the removal of organs and trafficking in human organs, frequently as transnational criminal activities.

This practice represents a high risk to both individual (patients and donors) and public health, violates human rights and fundamental freedoms, and constitutes an affront to the very notion of human dignity and personal liberty.

The World Health Organization (WHO) estimates that 5% to 10% of organs transplants performed annually take place in the international organ trade[6]. However, the true dimension of the organ trafficking remains unknown because there is no a global registry of transnational transplant activities. The black market kidney, which involves various actors, is a highly lucrative business. Recipients usually pay between $70,000 and $160,000 for an organ, more than would be paid for a legal transplant. The "donor" (kidney seller) also receives money, but a small percentage of what the recipient pays. Most of the money goes to hospitals, brokers and other middlemen engaged in organ trade.

This criminal activity usually occurs in the context of what has been called "transplant tourism", with patients travelling across jurisdictions to receive an organ in countries where the legislation against the sale and purchase of human organs is inexistent or poorly enforced. The typical donors, source of organs for transplant tourists, are people desperate for money to the point of selling a part of their body. Women, men or children, in situations of extreme poverty or social vulnerability, such as refugees, illegitimate or illiterate migrant workers, sell a kidney to solve their desperate economic needs.They are, usually, from less well-developed countries.

Organ trafficking commonly involves different countries. In some cases the recipient travels to a country where the donor and transplant centre is located, or the donor travels to the recipient country. In other cases both, recipients and donors, from differents countries, move to a third country where the transplant centre is located.

The simultaneous involvement of different countries raises numerous problems in terms of criminal prosecution due to the lack of extraterritorial jurisdiction of national courts to judge crimes committed outside the country. On the other hand, although organ trade is illegal in almost all nations of the world, in most cases organ trafficking is not typified as a crime. There is no criminal sanctions for those committing such offence (e.g. buying a kidney).Furthermore, in some countries, domestic laws only prevent a person who is in their country (country of resident) from engaging in an illegal trade of human organs. Loopholes in the legislation mean that if a patient receives an organ in an illegal or unethical manner outside of the country of residence, he faces no criminal sanction when he returns home, as well as organ sellers and brokers, and transplant professionals engaged in organ trafficking.

Indeed, organ trafficking is a crime rarely punished. The black market has grown taking advantage of the lack of laws that prohibit transplant-related crimes as well as weak law enforcement.

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism[7], adopted by the international transplant community at an international meeting held in 2008, is the first document in response to growing concerns about trafficking in human organs. It defines and prohibits transplant tourism and organ trafficking, and set of principles with the aim to promote ethical practices in organ donation and transplantation around the world. Since 2008, more than 135 professional societies have formally endorsed the Declaration.

However, despite its recognized success and influence in the fight against organ trafficking, it has no force of law.

The new Council of Europe Convention against Trafficking in Human Organs[8], opened for signature on 25 March 2015, in Santiago de Compostela (Spain), provides a universal, harmonized and punitive response to organ trafficking. It is essential as first international binding criminal law that empowers States to deal specifically with this crime. It requires ratifying States to establish as criminal offences under their domestic law several illicit activities in respect of human organs, up until now unpunished.

So far the Convention against Trafficking in Human Organs has been signed by 18 States, which have not yet ratified it: Armenia, Austria, Belgium, Greece, Italy, Ireland, Latvia, Luxembourg, Montenegro, Poland, Portugal, the Russian Federation, Spain, Switzerland, Turkey, Ukraine, United Kingdom, and, recently, Costa Rica.

For the Convention to enter into force, following the signature, it is required its ratifications by five countries. Since 1 March 2018 the treaty is into force in five countries: Albania, Czech Republic, Malta, the Republic of Moldova, and Norway.

Whereas the previous international legal instruments did not provide any definition of organ trafficking nor any criminal sanctions, the new Convention identifies all practices or activities that constitute trafficking in human organs, which ratifying States are obligated to criminalise, and stipulates sanctions including loss of liberty. Therefore, today, there are no reasons for States do not have appropriate laws that prohibit transplant related crimes.

It complements the provisions in other international instruments, such as, the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention)[9], its Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin[10], and in particular the provisions of the Convention against Trafficking in Human Beings for the Purpose of Organ Removal (HTOR)[11], opened for signature in Warsaw on 16 May 2005, which entered into force on February 2008.

So far this Convention has been ratified by 47 States, including Belarus (on 26 November 2013, is into force on 1 March 2014).

The Convention HTOR is very important in the fight against transplant related crimes, however, it leave serious loopholes for condemnable practices that are now explicitly identified as criminal offences related to organ trafficking by the Convention against Trafficking in Human Organs.

These two types of trafficking are different and can be committed separately. In HTOR the organ was obtained through the use of coercion (such as, the use of force), abduction, of fraud or abusive means. It is the person who is trafficked for the specific purpose of removing his organs. The donor is a victim.

In Organ Trafficking the organ was not obtained through the use of coercion, abduction, of fraud or abusive means, but with the consent of the "donor" in exchange of financial gain (donor pay). It is the organ that is being trafficked.

Therefore, the added value of the Convention against Organ Trafficking is that it covers scenarios not covered by the Convention against Trafficking in Human Beings for the Purpose of Organ Removal, such as: (a) where the living donor was paid but no coercive, fraudulent or deceptive means have been used [e.g. when the donor has taken initiative to sell an organ by contacting potential recipients or intermediaries (instigation to organ trafficking)], (b) achieves illicit transplant practices that currently escape criminal prosecution, (c) covers illicit activities in respect of organs from deceased donors obtained without valid consent or authorization or in exchange for financial gain.

Concerning what practices constitutes crime of organ trafficking the new Convention identifies several acts, such as: (a) the removal of an organ without valid consent of the living donor or, in the case of the deceased donor, without authorization under its national law, (b) the selling or purchase of an organ, (c) the illicit solicitation or recruitment of organ donors or recipients when performed for financial gain or comparable advantage (e.g. advertising of the need for, or availability of a kidney with a view to offering or seeking financial gain), (d) the offering or requesting of financial gain or comparable advantage (to/by health professionals or public officials), (e) the transplantation of illicitly removed organs, (f) the transportation, transfer, receipt, import and export of illicitly removed organs, (g) the aiding or abetting the commission of organ trafficking.

Under the Convention will be criminally liable all persons engaged in organ trafficking, including: (a) persons who are involved in solicitation or recruitment of "donors" or recipients in exchange for financial gain, (b) intermediaries who purchase or sell an organ from living donor, (c) physicians engaged in te removal or transplantation of an organ from a donor who was paid, (d) healthcare professionals involved in the aiding or abetting the commission of organ trafficking (e.g. written a referral letter to the clinic or surgeon who will perform the illicit transplant), (e) publics officials who request or receipt undue benefits to facilitate illicit removal or transplantation of organs.

What about donors and recipients? Donors who have sold a kidney and recipients who know that the organ received was obtained illicitly (for example, donor payment).

Are they offenders?

Concerning this controversial question the Convention has left open for ratifying States to decide whether or not to criminalise them under their domestic law. This mean that States are not obliged to criminalise the "donors" and the recipients. Consequently, at the time of transposition of the Convention into their domestic law, the States have to decide whether the recipient should be subject to prosecution (brought to court and punished) or whether the patient should be treated as a witness. In this case, the recipient has the duty to testify and to cooperate with the law enforcement authorities by providing them relevant information, such as the names of city, hospital, or medical staff engaged in illegitimate transplantation.

Other added value of the Santiago Convention is the extraterritorial jurisdiction, a crucial tool to combat transplant related crimes.It covers acts committed abroad by nationals or residents engaged in organ trafficking, solving the problem of impunity of transplant tourism. Therefore, it allows the investigation and punishment of a recipient who has been transplanted in another country with a purchased kidney (even if organ trade is legal in that country), or a surgeon involved in that transplant knowing it's illicitly origin. States will have to cooperate at international level in criminal investigation (collection, analysis and exchange of information on trafficking networks), including the extradition of accused persons.

In addition to the new Treaty, others very important measures are being taken by the Council of Europe to prevent and combat transplant-related crimes. The creation of an international network of national focal points (NFP) on transplant related crimes is one of the most important measures, as well as an international database on Travel for Transplantation, launched in June 2017.

This international network of NFP embraces more than 30 States to one common purpose - "together against trafficking human organs".

It has been established by the CD-P-TO, in the context of the Resolution CM/Res(2013)55, adopted by the Committee of Ministers on 11 December 2013, which calls member States to adopt procedures for the regular collection of data on illicit transplantation performed outside the framework of a domestic transplantation system and to communicate the results to the CD-PTO. Another important recommendation that should be highlighted in this field is the Resolution CM/Res(2017)23, adopted by the Committee of Ministers on 14 June 2017, which calls Member States to establish *procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care*.

In the context of both Resolutions, the international network of NFP play a crucial role at national and international level in ensuring an integrated support to the fight against organ trafficking.

NFP role is supporting national efforts against organ trafficking, in particular: (a) the regular collection of data on illicit transplantation activities, through national transplant centers, (b) to create awareness among transplant professionals, on their role in helping prevent, detect and combat organ trafficking, (c) help establish a national protocol or a code of conduct to provide an adequate framework within the medical field to prevent, detect and report organ trafficking, (d) help establish multidisciplinary synergies and a multiagency approach to ensure effective fight against transplant-related crimes.

The aim of the data collection on patients who received a transplant abroad and returned to their country to receive follow-up care, is: (a) quantify possible cases of resident patients who might have travelled abroad to be transplanted with an organ retrieved from a paid living donor, (b) countries involved, (c) profile of recipients/donors (e.g. age, gender, relationship between donor and recipient, country of origin), (d) reasons to travel for transplantation, i.e., the circumstances prior to travel (e.g. active on the waiting list or not active on the waiting list), (e) to evaluate the quality of transfer of care, i.e., the availability and quality of medical records provided to the patient by hospitals or doctors engaged in transplant tourism, (f) impact on post-transplant outcomes (e.g. graft survival, patient survival, post-transplant complications).

Such information is communicated by NFPs to the CD- P-TO anonymously, with no personal information about the identity of the patients and donors. The international exchange of this information will help to better understand and analyse the phenomenon of travel for transplantation and its consequences.

Concerning health professionals, what is their role in the fight against transplant-related crimes?

Health professionals who treat patients in pre and post-transplant are in a unique position to help prevent and combat organ trafficking. In their daily practice, in pre-transplant, they manage patients who may be considering traveling abroad to purchase an organ (at risk for transplant tourism), and evaluate prospective donors and recipients (including non-resident living donor). They also care, in post-transplant, for patients who have received an organ transplant abroad and return home country for follow-up care.

However, how to deal with suspected or confirmed cases of organ trafficking?

Health professionals do not know whether or not to report these cases to law enforcement authorities due to their duty to preserve the secrecy oath (medical confidentiality).Knowledge and understanding on how to prevent, detect and report organ trafficking is practically nonexistent.

Transplant professionals should be aware of the legal and regulatory requirements that govern medical practice in their jurisdictions. Therefore, it is crucial to develop and implement national protocols, or a specific code of conduct, to provide health professionals with a framework (guidance's) to approach the subject of transplant tourism and organ trafficking with patients, as claimed by the Resolution CM/Res (2017)2 *on establishing procedures for the management of patients having received an organ transplant abroad upon return to their home country to receive follow-up care*, adopted by the Committee of Ministers on 14 June 2017.

National Focal Points can play a key role in promotion and implementation of such protocols, crucial to eliminate unreported or non-investigate organ trafficking.

These protocols should describe the actions or conduct that physicians should take in pre and post-transplant, and a reporting mechanism to allow physicians report these cases to law enforcement authorities.

This raises another important question. What are their obligations when they treat a patient who is considering traveling abroad to purchase an organ?

Health professionals have the duty to discourage and prevent any harm of patients, but also the duty to protect the possible victim-donor.

The most effective method to discourage/to prevent organ purchase is: (a) to inform patients about the ethical, medical, psychosocial and legal risks associated with organ trafficking, including medical risks for the donors, (b) by not providing patients with any information that could enable them to purchase an organ, for example, write a referral letter to the clinic or surgeon who will perform the illicit transplant or perform additional medical tests to send to the foreign transplant centre (e.g. tests to facilitate matching with a unrelated kidney donor), (c) in case of kidney transplant package deals abroad, frequently advertised on social networks, healthcare professionals should advise the patient not to contact the company and not use their services.

Concerning the obligations of health professionals when they treat patients who have received an organ transplant abroad in circumstances consistent with organ trafficking, should be highlighted that patients have the right to receive medical care in all circumstances, even after they have committed a crime. Health professionals cannot refuse treatment.

The primary duty of health professionals is to provide care, including a patient who has purchased an organ: (a) always in life-saving care, (b) in non-emergency situations physicians may refer the patient to another physician.

Health professionals also have the duty to ensure traceability and biovigilance for all patients who travel for transplantation. Therefore, the same data that are routinely collected must be recorded in national registries.

IN CONCLUSION:

To achieve an effective fight against organ trafficking, the legislation, law enforcement authorities, and healthcare authorities, must go hand in hand.

The actions that really can make a difference – changing the "black chapter" of transplantation history-, are: (a) the establishment of multidisciplinary and integrated synergies to ensure cooperation between all actors involved: healthcare authorities, law enforcement authorities (judges, prosecutors, police), health professionals, National Focal Points, Medical Associations, policymakers, others (e.g. Media), (b) development of a clear legal and ethical framework and mechanisms to allow health professionals to report transplant related crimes, (c) implementation of national laws that prohibit organ trafficking, through the adoption and implementation of the Convention against Organ Trafficking (national laws - criminal code and transplant laws-, should be reviewed according to the Convention), (d) pursuing national self-sufficiently (for instance, developing better systems of deceased organ donation).

---

[1] Guide to the Quality and Safety of Organs for Transplantation, 6th Edition, 2016; Guide to the Quality and Safety of Tissues and Cells for Human Application, 3rd Edition, 2017, EDQM, Council of Europe, available at https://www.edqm.eu/freepub/

[2] 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 (ETS No. 164), Oviedo, 4 April 97, available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164

[3] Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/186

[4] Council of Europe Convention against Trafficking in Human Organs (ETS No. 216), Santiago de Compostela, 25 March 2015, available at https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/216/

[5] Source: Newsletter Transplant- Free download at www.edqm.eu/freepub

[6] Shimazono Y. 2007. *The state of the international organ trade*: *a provisional picture based on integration of available information*. Bulletin of the World Health Organization, 85(12): 955-962.

[7] The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 edition), available at http://www.declarationofistanbul.org/