Trafficking and Organs, Tissues, and Cells: An Examination of European and UK Legislation and Gaps

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Abstract

Substantial custodial sentences were handed down from the English Central Criminal Court for organ trafficking. Attempts to exploit vulnerable people for the purposes of organ removal, and for organ, tissue, and cells (otc) trafficking are ongoing in many jurisdictions. It is also clear from the 2019 EU evaluation of the Union legislation on blood, tissues, and cells that there is increasing commercialization in the procurement of human material for medical use, using global supply chains. Full traceability of all human material, for which there is a shortage to meet global medical needs, is required. The medical profession has drafted the Istanbul Declaration on Organ Trafficking and Transplant Tourism 2008, calling for transplant tourism to be prohibited, and full engagement with transnational law enforcement to address developing transnational organized crime in this area. This paper addresses the global, Council of Europe, EU, and UK provisions in this area.

Keywords

organs tissues and cells – transplant tourism – Europe – UK
Introduction

In 2023, Nigerian senator, Ike Ekweremadu and two others were convicted at the English Central Criminal Court of organ trafficking leading to substantial custodial sentences.¹ The intended victim, who had been trafficked to England, reported the situation directly to the English police. Attempts to exploit vulnerable people for the purposes of organ removal, and for the related organ, tissue and cells trafficking are ongoing in many jurisdictions due to a shortage of human material, including plasma, to meet global medical needs. The 2019 EU evaluation of the Union legislation on blood, tissues, and cells² makes it clear that there is increasing commercialisation in the global procurement of human material for medical use. From a transnational criminal law perspective, there is a need to raise the level of awareness of these activities amongst legislators, law enforcement and prosecutors.³ Effective transnational legal and law enforcement frameworks need to be developed. Global legal gaps are emerging, and it is through these gaps in regulatory frameworks that “the skilled criminals who organize transnational organ trade”⁴ will operate. The medical professions have been asking for this matter to be addressed, with involvement from transnational law enforcement. At a medical practitioner level in many countries “national rules and guidelines for physicians on how to deal with transplant tourism do not exist.”⁵ All countries, except Iran, have criminalised kidney sale,⁶ however, none apply these laws extraterritorially,⁷ a pre-requisite for transnational legal and law enforcement frameworks. The question arises how to effectively legislate for what the medical profession are calling transplant tourism. As this activity operates much in the same way as transnational organised crime, and runs in parallel to, and sometimes overlaps

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¹ R v Obeta and Ekweremadu, Central Criminal Court, 5 May 2023.
⁷ Ibid., p. 282.
already criminalised human trafficking, the same approach should be brought to transplant tourism. Gaps in national and transnational legal frameworks need to be addressed, national criminal provisions given extraterritorial effect, practice manuals developed between transnational law enforcement structures and the global legal profession, then transnational legal and law enforcement framework can be developed, to tackle what is very serious human exploitation and abuse.

The phenomenon of organ and tissue trafficking from live unrelated donors (LURD) emerged in the 1990s, with medical advances, starting in 1963,8 culminated in the 1980s with the development of “cyclosporine, an immunosuppressant drug that could counteract recipients’ rejection of transplanted body parts”.9 The demand for organs, and tissue then advanced, to outstrip legal supply.10 Sub-standard transplants can lead to “surgical complications, acute rejection and invasive infection”, bringing highly infectious complications back into the health care system of their country of origin upon their return.11 All transplants require ongoing immunosuppressive treatment which in the case of a kidney transplant patient cost, in the US market in 2013, being approximately “$15,000 to $20,000 annually.”12 All those undergoing illicit OTC abroad will therefore have to present themselves at the health care system of their country of origin upon return. One way of combatting this crime is for prohibiting health insurance providers from funding transplant tourism.13

The EU advocate full traceability of human material for medical purposes. The current review of the EU’s legal provisions on blood tissues and cells is being undertaken by DG Health and Food Safety, with input, inter alia, from DG Justice and Home Affairs. Issues of force, duress, and exploitation arise, together with the issue of valid consent. These are issues for transnational law enforcement, which should be fully engaged with legal developments with a view to developing effective transnational law enforcement in this area. More robust transnational legal and law enforcement frameworks need to be

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13 Ibid.
developed to combat the global supply of human material in exploitative and abusive conditions.

Transplant tourism, a term used in the medical practitioners’ Declaration of Istanbul on Organ Trafficking and Transplant Tourism 2008 (DO1), is often an illegal sub-set of medical tourism, which “has emerged as a global health care phenomenon”.14 Illegal kidney transplants alone were estimated by the World Health Organisation (WHO) to comprise 5–10% of the 60,000 kidney transplants performed globally in 2007,15 with “private firms” facilitating this practice “with little or no danger of prosecution.”16 Often organs are sold into the illegal trade by “persons in a state of abject poverty.”17 The root of OTC trafficking “is disparity in living standards”, however the “criminalization of trafficking for organ removal must come first”,18 with the “major ‘recipient’ countries [doing what they can] to close the transplant tourism loopholes in their own systems.”19

This paper will examine work already undertaken by the medical profession to address the issue of transplant tourism, to establish where transnational and national legal frameworks can best fit in with current medical practice. The current global legal provisions are then examined, followed by those of the Council of Europe (CoE) and the EU. The paper will then examine the approach taken in the main UK legal jurisdictions, after which the paper will conclude.

The View from the Medical Profession

As stated by Bagheri and Delmonico, transplant tourism violates the “Universal Declaration of Human Rights (1948), the UNESCO Universal Declaration of Bioethics and Human Rights (2005), the Istanbul Declaration on Organ Trafficking and Transplant Tourism (2008), and the WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation (2010).”20 The WHO, through

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14 J.A. Akoh, op. cit., p. 9.
18 R. Ainley, op. cit. p. 464.
19 Ibid., p. 427.
its World Health Assembly (WHA) “first declared the prohibition of organ trade in 1987, affirming that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights”\(^{21}\) in WHA resolution 40-13. This was followed up in 1991 Resolution WHA44.25, Guiding Principles on Human Organ Transplantation, “which had a great influence on professional codes and legislation.”\(^{22}\) The need “to protect the poorest and vulnerable groups from ‘transplant tourism’”, and to further focus on the commercialisation of OTC more broadly, was addressed in 2004 in Resolution WHA57.18 on Human Organ and Tissue Transplantation. However, as pointed out by Ambagtsheer \textit{et al}, it does not “prohibit the purchase of organs by patients abroad.”\(^{23}\) The WHA\(^{24}\) has also urged member states to “implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability”. It is arguable that this should now be developed further to cover transnational accountability for human material and transnational traceability.

The DOI has become a key document in this area, having been drafted by the leading medical professionals at a joint summit held by the Transplantation Society and the International Society of Nephrology in 2008. The DOI is the first international document which “defines and prohibits transplant commercialism and organ trafficking.”\(^{25}\) Its provisions are addressed to transplant professionals and transplantation societies,\(^{26}\) and has been “proven to have significant influence”.\(^{27}\) However, it needs to be remembered that obtaining new organs are not the sole purpose of transplant tourism.

The DOI uses the term “travel for transplantation” for legitimate travel for organ and tissue transplantation, and uses the term “transplantation tourism” for organ trafficking and/or transplant commercialism” (which is seen as “interfering with the country’s ability to provide transplant services

\(^{21}\) F. Ambagtsheer and W. Weimar, \textit{op. cit.}, p. 572.
\(^{22}\) Joint Council of Europe/ United Nations Study; Caplan A. \textit{et al.}, Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs, Secretariat of the Council of Europe Convention, Council of Europe, Strasbourg, 2009, p. 65.
\(^{23}\) F. Ambagtsheer \textit{et. al.}, \textit{op. cit.} p. 2.
\(^{25}\) F. Ambagtsheer and W. Weimar, \textit{op. cit.}, p. 571.
\(^{26}\) F. Ambagtsheer \textit{et. al.}, \textit{op. cit.} p. 2.
\(^{27}\) Ibid.
for its own population), which it condemns. It does not view all “travel to foreign countries to undergo transplantation” as being unethical. The DOI calls “for a legal and professional framework in each country to govern organ donation and transplantation activities.” It is not itself a legal framework. In addition, given that it is written by medical professionals, rather than lawyers, it does not consider the need for a transnational legal framework to combat the illegal trade in OTC, however such a legal framework is clearly required. Despite its lack of legal authority, the DOI has had substantial impact amongst the medical profession in many countries “through the voluntary adherence by professional and governmental bodies to its principles and from being directly incorporated into national laws and regulations.” With 128 endorsements from “national and international professional organizations but also from governmental bodies”, the DOI would be the appropriate starting point for drafting transnational legal frameworks in this area. These gaps in the framework have been acknowledged by the Declaration of Istanbul Custodian Group, who, at their fifth anniversary meeting, in 2013, in Qatar, called for increased cooperation with law enforcement, and also for “the use of international conventions to ensure that organs are obtained and used in an ethical, safe and transparent fashion.” They also called for reporting mechanisms for doctors to report “patients returning with a donor organ from an “unverifiable source” or manifesting other indications of a vended organ.” The same could be said for all examples of transplant tourism. Training of law enforcement and human rights organisations of transplant tourism was also called for. Transplant tourism has been likened to drug trafficking.

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30 Ibid., p. 117.
31 Ibid., p. 119.
33 Ibid.
34 Ibid., p. 1311.
35 Ibid.
36 Ibid.
37 Ibid., p. 1312.
mechanism used to combat drug trafficking therefore need to be adopted to combat transplant tourism. Francis and Francis point out that “states with vulnerable populations have taken action to protect their citizens” from those who prey on the vulnerable. There is also an obligation on states with greater capacity to assist other states in their OTC transplant supply chain. Francis and Francis also call for the “establishment of an effective international enforcement regime” in this area. Ambagtsheer et al speak about the DOI “bridging the gap between the medical field and the criminal justice realm”, leading to involvement of Interpol, UNODC and Europol. Law enforcement, both national and transnational, however, needs a clear legal framework against which to operate.

The Current Global Legal Framework

Organ removal, as form of exploitation was recognised as a form of human trafficking in the Palermo Protocol on Trafficking in Human Beings (THB). The Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography requires the criminalisation of the “transfer of organs of the child for profit”. Both legal provisions, enacted in 2000, focus on the narrower, and higher profile instance of trafficking for the purposes of organ removal. They do not cover THB for tissue or cell removal, or even broader issue of trafficking in organs, tissues, and cells (OTC). There are two distinct situations with “in one case the organs, tissues and cells and in the other case is a person who is trafficked for the specific purpose of removing his/ her organs.” As the Joint CoE/ United Nations report on trafficking in OTC acknowledges that THB for organ removal is but a small part of the bigger issue of OTC, but that “the former could not be examined without the latter.” There is a lot of confusion

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40 Ibid.
41 F. Ambagtsheer and W. Weimar, op. cit., p. 574.
44 A. Bagheri and F.L. Delmonico, op. cit., p. 894.
in both the legal and scientific communities between these two crimes. In addition, the distinction is becoming increasingly blurred, as evidenced by recent reports on foetus trafficking in Viet Nam. When comparing the global volume of the two activities, THB for organ removal “might be considered a marginal phenomenon.” In addition, THB “involves a combination of three basic elements (action, means and purpose), which may not necessarily be present in cases of trafficking in OTC.” As stated by Bagheri, “the solution for preventing the two types of trafficking have to be different.”

Apart from the DOI, and the WHA resolution, “there are no international regulations that condemn or prohibit transplant tourism.” There had been suggestions for a United Nations (UN) Convention against Organ Trafficking, which should be extended to OTC, however national laws were not sufficiently advanced in this area. A web of transnational legal frameworks remain the more likely option in order to combat specific global supply chains. However, there are gaps in the legislative coverage of OTC at various levels. This includes the fact that “there is no internationally agreed definition of trafficking in OTC.” A definition used for OTC trafficking is that of the joint CoE/UN report, which has defined OTC trafficking as occurring “when there is (a) the illicit removal, preparation, preservation, storage, offering, distribution, brokerage, transport or implantation of organs, tissues or cells (cells for the purpose of therapeutic transplantation); and (b) the possession or purchase of organs, tissues or cells with a view to conducting one of the activities listed in (a); solely for financial or other economic gain (for this or a third person's benefit).”

Medical practitioners in many countries do not have clear laws and guidelines on how to deal with transplant tourism. While doctors would be obliged to care for their patients, failure to do so being in breach of human rights provisions, an obligatory reporting mechanism should be put in place, along

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46 Ibid.
49 Ibid., p. 11/12.
50 A. Bagheri, op. cit. p. 243.
51 World Health Assembly Resolution 57.18, op. cit.
52 F. Ambagtsheer et al., op. cit. p. 3.
56 Ibid.
57 F. Ambagtsheer et al., op. cit. p. 4.
the lines for that for legal advisors etc. who are required to report suspected money laundering activities in a wide range of jurisdictions. Current legal provisions would justify a doctor notifying the police if the patient is about to engage in transplant tourism. The view from the medical professions is that the “doctor’s privilege of nondisclosure is not absolute” and there may be a duty “to breach the professional secrecy oath when the doctor is confronted with information that, if not reported, will lead to “direct and severe” harm to another individual” [emphasis in the original]. 58 However many believe that there is a lack of clarity on this point, which should be addressed in any future legal framework. Outside the EU, or similar regulatory framework for OTC, it is not clear that a medical professional would know the source of the transplanted organ, and in the absence of transnational law enforcement support, be able to come to an informed decision whether the organ had been obtained from an exploited individual or not. The medical profession may not, however, be able to establish the actual source of the organ of a returning patient without transnational law enforcement support, particularly given the ability of organised crime to forge documents, assuming the doctor did engage in a due diligence process.

There are significant parallels between medical specialists/ OTC trafficking and legal advisor/ money laundering reporting obligations, as OTC trafficking, as with money laundering, “requires elements traditionally associated with organized crime.” 59 These include the verification of identities and risk assessments. Legal professional privilege, the corollary of doctors claimed professional secrecy obligations does not apply in cases where there is knowledge or suspicion that a money laundering offence has occurred, and the need to file suspicious activity reports, without notifying the legal advisor’s client. These standards are all set out in the Financial Action Task Force (FATF) standards for anti-money laundering and counter-terrorism financing, 60 and have been implemented in most jurisdictions around the globe. Similar standards and procedures should be expressly written into domestic laws for OTC trafficking to overcome some doctors claims of professional secrecy or lack of responsibility to report. 61

The international medical profession is seeking legal and law enforcement support to address the issues that they face in practice. Holmes et al. recommend that criminal justice and medical professionals should “collaborate to produce

58 Ibid.
60 https://www.fatf-gafi.org/.
61 F. Ambagtsheer et al., op. cit. p. 4.
a detailed, step-by-step breakdown of the entire legal transplant process, encompassing initial assessment practice, transplant procedures, the medical actors, and the documentation trail for the whole process."62 For example, couriers, carrying the body parts packaged in picnic coolers, can be “stowed in overhead bins on a commercial aircraft”.63 These should be checked in the absence of properly sourced accompanying paperwork. However, it should be noted that the shelf life of a heart for the purpose of transplantation (ischaemic times) is 2–3 hours, and a liver 6–7 hours.64 Therefore it is much more likely that the “donor”, along with the “donee” will be brought to the place of operation, as with the Ekweremadu case referred to earlier, bringing back into focus the issue of THB for organ (or tissue) removal. It is worth noting at this stage that the definition of THB provides “that exploitation should include ‘at a minimum’ the purposes listed”, raising the possibility of further purposes, say trafficking for tissue and cell harvesting being added by national legislators, investigators, and prosecutors in implementing national THB laws.65 Exploitation is also the key to establishing whether OTC trafficking should be dealt with by the transnational criminal legal system. The full transnational law enforcement framework, which is highly developed in the case of organised crime, anti-money laundering and drugs trafficking, should be brought to bear on exploitative activities, as trafficking will potentially involve multiple jurisdictions, “the location of organ procurement, the location of the recipient, the place where actual transplantation occurs, and the location of any organ broker.”66 As this involves global supply chains, “global collaboration is crucial”.67

Council of Europe Conventions and Protocols

In addition to the CoE’s Convention on Action against Trafficking in Human Beings,68 Article 4 of which replicates Article 3 of the Palermo Protocol on THB, the CoE has several international treaties of relevance to this area. Of particular relevance is the CoE Convention against Trafficking in Human

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62 P. Holmes, et. al, op. cit. p.3.
65 Ibid., p. 55.
67 A. Bagheri and F.L. Delmonico, op. cit., p. 893.
68 Warsaw, 16.5.2005, CETS 197.
Organs, 2015 (the Santiago Convention). This was preceded at the CoE by the 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, 1997, otherwise known as the Oviedo Convention, is at the time of writing in force in 30 CoE member states, and has been signed by a further 6 CoE member states. One of its four protocols, the 2002 Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2002 Additional Protocol) is relevant to this discussion. Its Article 3 addresses the issue of transnational exchange of organs from a medical point of view. If pleaded before the ECtHR the principles of these conventions need to be pleaded in conjunction with the principles of the European Convention on Human Rights. A relevant case is *Elberte v Lativa*, where the ECtHR ruled that the removal of a deceased husband's tissue without consent of the widow, who brought the case, was "an interference with the applicant's right to respect for her private life under Article 8 of the Convention", even where the tissue removal had been carried out in accordance with domestic law.

The principle underpinning both the CoE and EU provisions in this area is expressly stated in Article 21 of the Oviedo Treaty, that “the human body and its parts shall not, as such, give rise to financial gain”. This approach was confirmed in its 2002 Additional Protocol, at Article 21, with organ and tissue trafficking also being expressly prohibited. There are no further provisions in this document as to how organ and tissue trafficking is to be addressed. The 2002 Additional Protocol does anticipate “compensation of living donors for loss or earnings and other justifiable expenses”, which would not fall foul of the prohibition on financial gain. Advertising, however, of organs or tissue, “with a view to offering or seeking financial gain or comparable advantage” is prohibited.

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69 CoE Convention against Trafficking in Human Organs, (Santiago Convention) 2015, cets 216.
71 Not including the United Kingdom.
72 ETS No. 186.
73 *Elberte v Lativa* (Application no. 61243/08), Strasbourg, 13 January 2015.
76 Ibid. Article 21.2.
The Oviedo Treaty states that organ removal can only be done with the express consent of the donor, given “expressly and specifically either in written form or before an official body”,77 and that no organ should be removed from those who do not have the capacity to consent,78 with a limited number of exceptions provided in Article 20.2. This is reaffirmed in Articles 13 and 14 of the 2002 Additional Protocol. How freely this consent has been given remains an issue, particularly in the context of THB for organ removal, or OTC trafficking. As pointed out in the Joint CoE/ UN study “extreme poverty and discrimination, including gender discrimination” are factors in organ trafficking, many of whom “know far too little about their rights or how to appropriately assert them” leading to a lack of informed consent.79 The Joint CoE/ UN report goes on to say that “commercial living donors are frequently illiterate, which makes them especially vulnerable.”80 Detainees should also be considered not capable of consenting to organ donations.81 In addition, “donations of organs by war prisoners is totally void” under humanitarian law.82

The limited number of exceptions provided in the Oviedo Treaty, Article 20.2, are reiterated in Article 14 of the 2002 Additional Protocol, with reliance being made on “protective conditions prescribed by law” in the national law of the relevant signatory state. EU member states have “a degree of variation” in their “consent regimes” “reflecting the national specificities of historical, socio-cultural and medical contexts”.83 It could happen that a legitimate organ removal in one country could therefore be treated as trafficking in OTC in another country.84 The development of a transnational legal and law enforcement framework in this area will therefore have its own challenges.

The Santiago Convention 201585 was enacted amid growing concern about the violation of “human dignity and the right to life” and the “serious threat to public health”86 that the mainly illegal transnational supply in organs was causing. It has a threefold purpose, to criminalise, prevent and combat THB, to protect the rights of victims, and to “facilitate co-operation at national and

77 Oviedo Convention, op. cit. Article 19.2.
78 Ibid. Article 20.1.
80 Ibid. p. 60.
81 A. Pietrobon, op. cit. p. 495.
82 Ibid., p. 497.
84 A. Pietrobon, op. cit. p. 492.
85 Santiago Convention op. cit.
86 Ibid., Preamble, paragraph 5.
international levels on action against the trafficking in human organs." It does not address the issue of trafficking in tissues or cells, as it was not considered feasible at the time of drafting, as a "significant number of States" had then yet to regulate "human tissues and cells in the same way as the area of human organs."88

The Santiago Convention, Article 2, provides a definition for "trafficking in human organs" which is to mean "any illicit activity in respect of human organs as prescribed in Article 4, paragraph 1 and Articles 5, 7, 8 and 9 of this Convention". Article 4 deals with the illicit removal of human organs, upon which the rest of the offences specified in the other articles rests. Illicit removal of human organs is defined as the criminal offence in three circumstances: firstly, of intentionally moving human organs from living or deceased donors 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 authorised under its domestic law". As Pietrobon states, this does not prevent a state party from broadening their definition of the crime from "intentionally" to cover "reckless" or adding "reckless or negligent conduct" to their own domestic definition of the crime of organ trafficking, say where a surgeon does not engage in due diligence to ensure a known and legitimate origin for the organ that he is about to transplant. However, problems may arise when the mens rea differs from one jurisdiction to another, say an "intentionally, recklessly, or carelessly" test as opposed to another jurisdictions "intentionally" only test interact during a transnational law enforcement operation and prosecution. Further issues will arise when differing definitions of exploitation and consent are adopted in different jurisdictions. Ineffective legal and registration systems for organ donation and transplant would also need to be addressed in Santiago Convention contracting parties' domestic legal systems. Also illegal under Article 4 of the Convention is the removal of organs where "the living donor, or a third party, has been offered or has received a financial gain or comparable advantage", which would be understood to be reasonable expenses or loss or earnings, in exchange for the organ. It also covers the offering or receipt by a third party of "financial gain or comparable advantage" in return for the removal of organs from a deceased donor.

The Santiago Convention further provides for the Article 2 offence of trafficking in human organs, and the Article 5 prohibition on the “use of illicitly removed organs for purposes of implantation or other purposes

87 Ibid. Article 1.
88 A. Bagheri and F.L. Delmonico, op. cit., p. 893.
89 A. Pietrobon, op. cit. p. 498.
than implantation,” the Article 7 prohibition on the “[i]llicit solicitation, recruitment, offering and requesting of undue advantages,” and the Article 8 prohibition on the “[p]reparation, preservation, storage, transportation, transfer, receipt, import and export of illicitly removed human organs”. Aiding, abetting, or attempting any of the above is also an offence under Article 9. There is a difference in drafting what are seen as the primary offences, the Articles 4.1, 5, 7, 8 and 9, above, which provides that the “each Party shall take” the necessary measures to establish criminal offences in their jurisdictions, and the subsidiary measures of organ transplantation outside the domestic transplantation system, (Articles 4.4 and Article 6), where the option of the state party to take administrative rather than criminal measures remaining open. The intention is to criminalise “the entire chain of culpable actors in the enterprise” of organ trafficking, in particular the surgeons and other medical professionals, except for the very vulnerable “donors” and “recipients”.

Sanctions for natural persons under the Santiago Convention are to include “deprivation of liberty that may give rise to extradition”. Legal persons will also be subject to “criminal or non-criminal monetary sanctions”, to include judicial winding up. In addition, the usual proceeds of crime procedures will be followed, and the premises used to carry out the procedure could be temporarily or permanently closed. Aggravating factors include causing “death of, or serious damage to the physical or mental health of the victim”, abusing ones position, or if the offence was committed in the context of organised crime, if the perpetrator has previously been convicted of a similar offence, or if “the offence was committed against a child or other particularly vulnerable person”. As with all CoE conventions, a child will be someone under the age of 18, however, as pointed out by Pietrobon, removal of an organ from a minor will not always be a criminal offence.

With a focus on combatting the transnational crime of organ trafficking, extra-territorial effect of national provisions, and how jurisdictions are to co-operate with each other in investigating and prosecuting this crime is important under the Santiago Convention. Jurisdiction is to be established within a state's territory, on board a ship flying its flag, on an aircraft registered

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90 Ibid., p. 486.
91 Santiago Convention op. cit. Article 4.
92 Ibid., Article 4.2.
93 Ibid., Article 4.3.
94 Ibid., Article 13.
95 A. Pietrobon, op. cit. p. 491. With divergence in practice between different states, the Santiago Convention was left deliberately vague in this area, allowing in some cases for special situations "strictly regulated by law", such as sibling donations. (p.491).
in that state, through the actions of one of its nationals, or the actions of a “person who has his or her habitual residence in its territory”. 

In addition states are to “endeavour” to establish jurisdiction when an offence is “committed against one of its nationals or a person who has his or her habitual residence in its territory”. 

It is anticipated that this would cover a medical practitioner who brought a patient “to a third country, in order to perform the surgery or just to advise or assist the local colleagues.” 

Derogations are however possible to the establishment of jurisdiction for offences committed, outside the territory, by one of its nationals or persons ordinarily resident in its territory. 

In addition, recognising the extreme vulnerability of victims of organ trafficking, prosecutions in the context of both THB for organ removal should not rely on “a report from the victim”, or “the laying of information by the State of the place where the offence was committed”. 

Evidence would be required to be developed by way of intelligence led policing techniques, such as surveillance, wire-tap evidence, etc. States who do not extradite their own nationals should establish jurisdiction in their own territory to prosecute suspected offenders.

Any conflict of jurisdictions arising under the Santiago Convention are to be resolved by consultation between the two states. 

The Santiago Convention international co-operation provisions rely on “relevant applicable international and regional instruments”, presumably to include those covering transnational organised crime, together with “arrangements agreed on the basis of uniform or reciprocal legislation and their domestic law, to the widest extent possible.”

These are to include not just investigations and prosecutions, but also, as with all transnational organised crime, seizure and confiscation orders. It is anticipated therefore that the Santiago Convention needs to be further elaborated on by either pre-existing bi-lateral and multi-lateral legal and law enforcement provisions, to include transnational law enforcement practice manuals, or by additional provisions specifically designed to address transnational organ trafficking. If those further legal and law enforcement provisions are not in place, and a request comes into a country for assistance then Article 17.3 provides that the Santiago Convention itself should be sufficient “legal basis for extradition or mutual legal assistance. 

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96 Santiago Convention op. cit. Article 10.1.
97 Ibid., Article 10.2.
98 A. Pietrobon, op. cit. p. 500.
99 Santiago Convention op. cit. Article 10.3.
100 Ibid., Article 10.4.
101 Ibid., Article 10.6.
102 Ibid., Article 10.7.
103 Ibid., Article 17.1.
104 Ibid., Article 17.1.
in criminal matters in respect of the offences established in accordance with this convention”. Whether Article 17.3 will in fact be sufficient will, of course, depend on the legal and constitutional provisions of that jurisdiction. There is a further legal requirement on signatory states to ensure that all legal and procedural measures will be taken within the relevant jurisdictions “to ensure effective criminal investigation and prosecution of offences established in accordance with this Convention”, which would include the transnational aspects of organ trafficking.

Victim protection measures are set out in Article 18, to include, as with THB requirements “assisting victims in their physical, psychological and social recovery”. The standing of victims in criminal proceedings is covered in Article 19, and witness protection provisions are covered in Article 20. Prevention of organ trafficking is also a focus of the Santiago Convention, at both national and international level.

The Santiago Convention is still at a very early stage of implementation, with at the time of writing, 15 countries ratified the convention, with 11 further signatures, to include the UK. Hopefully more signatures and ratifications will soon follow, and in due course its provisions will be extended to cover tissue and cell trafficking. Provisions have been made for review of progress in the adoption and implementation of the Santiago Convention.

It is envisaged that the Santiago Convention would apply to relations between different contracting parties in this crime area, but also by one contracting party when encountering transnational organ trafficking involving themselves and a third state. There could be differences in approaches to organ removal from children. In addition, the determination of valid informed consent by a “donor” would also differ between states, particularly at a global level, as the “local law might be less attentive to the protection of the donor when compared to European standards.” The question also arises as to who carries the burden of proof in establishing that valid informed consent of the “donor” was not in fact given to the organ “donation”. As this is a criminal case, the test would be beyond reasonable doubt. This is important as the “donor” is often a highly traumatised, and frequently a marginalised individual. Assuming that both the donor and recipient can be identified, along with all those who operate along the transnational supply chain, it needs to be clearer which jurisdiction’s test of valid informed consent is to be used, that of country

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105 Ibid., Article 16.
106 Ibid., Article 21.
107 Ibid., Article 22.
108 Ibid., Article 23–25.
of origin of the victim, where the removal of organ occurred, or the country of transplantation, or the country of origin of the recipient. It is through these gaps in regulatory frameworks that “the skilled criminals who organize transnational organ trade”\textsuperscript{110} will operate.

**EU**

At the European Union (EU) level there is a general prohibition in the EU’s Charter of Fundamental Rights, Article 3, a “prohibition on making the human body and its parts as such a source of financial gain”, in the fields of medicine and biology. This provision is part of the right of everyone to “his or her physical and mental integrity.” “Free and informed consent” is therefore required for any intervention, “according to the procedures laid down by law”. Relying on the public health competence in Article 168.4 TFEU, an area of supporting, coordinating or supplementing competence,\textsuperscript{111} the EU has enacted provisions to legalise and put on a state-to-state framework previously “informal, non-legally binding arrangements devised by experts, operating in a largely technocratic environment”\textsuperscript{112} to facilitate organ,\textsuperscript{113} blood,\textsuperscript{114} tissue and cells exchange.\textsuperscript{115} The EU have already conducted their first formal evaluation of the EU legislation on blood, tissue and cells, with revised legislation due from DG Health.

A Single European Code for tissues and cells has been adopted\textsuperscript{116} for the purpose of full traceability and transparently of all tissue and cells, except for cells for reproductive purposes, being transferred from one person to another,

\begin{itemize}
  \item \begin{footnote}Ibid.\end{footnote}
  \item \begin{footnote}TFEU Article 6.\end{footnote}
  \item \begin{footnote}A.M. Farrell, (Adding Value), op. cit., p. 76.\end{footnote}
  \item \begin{footnote}Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, oJ L 102, 07/04/2004 p. 48.\end{footnote}
  \item \begin{footnote}Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (Text with EEA relevance), oJ L 93, 09/04/2015 p. 43.\end{footnote}
\end{itemize}
regardless of the donor being alive or dead. Its provisions are also to apply for tissue and cells being imported into the EU from third countries. It does not, however, apply to “tissues and cells distributed directly for immediate transplantation to the recipient”.\footnote{117} However, where exemptions from the Single European Code are provided “Member States should ensure that appropriate traceability of these tissues and cells is guaranteed throughout the entire chain from donation and procurement to human application.”\footnote{118}

In the case of tissues and cells, Directive 2006/17/EC\footnote{119} provides that in addition to the requirement that “consent for the procurement has been obtained” “after all mandatory consent or authorisation requirements in force in the Member State concerned have been met”, with member states having ensured that “donors, their relatives or any person granting authorisation” has been “provided with all appropriate information” prior to that authorisation.\footnote{120} In addition, in the case of living donors, health professionals must ensure that the donor “has understood the information provided”, have “had an opportunity to ask questions and been provided with satisfactory responses”, and that the donor has “confirmed that all the information provided is true to the best of his/her knowledge”.\footnote{121} Further enquires at this stage as to the level of valid consent to donation, and the absence of force or duress would be useful.

The EU has legally set the standards for “quality and safety for the collection, testing, processing, and storage and distribution of human blood and blood components, stating that “an examination of the donor, including an interview” is to be carried out before any donation.\footnote{122} EU member states are to “encourage voluntary and unpaid blood donations”.\footnote{123} All blood and blood components donated are to be fully traceable, from the point of donation, all the way through processing to end use, with a unique identifier to be used for


\footnote{123} Ibid., Article 20.
each donor.\textsuperscript{124} This level of traceability is also to apply for blood and blood components imported from non-EU states.\textsuperscript{125} Similar provisions for other human material would be useful in order to tighten up the provisions dealing with OTC.

Unlike the EU tissue and cells, and blood legislation, the EU organ transplant legal framework does acknowledge the existence of organ trafficking, recognising that the establishment of “competent authorities, the authorisation of transplant centres”, and a fully traceable and transparent system of organ tracking should contribute “indirectly to combating organ trafficking”.\textsuperscript{126} The emphasis of the EU organ transplant legal framework is on altruism, with the primary purpose being “the quality and safety of organs”.\textsuperscript{127} Secondarily, reference is made to the “prohibition on making the human body and its parts as such a source of financial gain”, set out in the EU Charter of Fundamental rights and the Oviedo Convention. Full traceability is required under EU law “to cover all stages of the chain from donation to transplantation or disposal”.\textsuperscript{128} These provisions should be echoed in the EU legal framework for tissues cells and blood.

The preamble to Directive 2010/45 on organ transplantation does provide that a pre-transplant interview should be held with a living donor, or “where necessary and appropriate, with the relatives of the deceased donor”.\textsuperscript{129} The emphasis on this interview is on ensuring the quality of the organ being donated, with the “potential risks and consequences of donation and transplantation being covered”. Farrell points out that “no detail is provided in the substantive part of the Directive as to the specific protections that are to be afforded to such donors.”\textsuperscript{130} The issue of the living donor giving free and informed consent, without duress is not addressed. Consent of the donor is of course, required, and this has to be verified “in accordance with the national rules that apply where the donation and procurement takes place”.\textsuperscript{131} Despite the existence of


\textsuperscript{125} Ibid., Article 7.


\textsuperscript{127} Ibid., Article 4.

\textsuperscript{128} Ibid., Preamble, paragraph 19.

\textsuperscript{129} Ibid., Preamble. paragraph 12.


\textsuperscript{131} Directive 2010/45/EU, op. cit., Article 4.2 b.
a European Parliament resolution on organ donation and transplantation, which *inter alia* addressed the issue of organ trafficking, experts working at an EU level appear to have little current interest developing the legal and law enforcement framework to combat the wider issue of otc trafficking. This should be addressed. The European Parliament resolution, in the context of organ trafficking, had recognised the “link between organ shortage and organ trafficking”. It calls on all EU member states to ratify the CoE Convention on Action against Trafficking in Human Beings and the Palermo Protocol. It also calls on EU member states to ensure that their criminal law provides for the adequate prosecution of organ trafficking, to include the sanctioning of medical staff involved, stressing that “consideration should be given to making EU citizens criminally liable for purchasing organs inside or outside the EU”. This is to include preventing “health insurance providers from facilitating activities that directly or indirectly promote trafficking in organs” to include repayment for travel abroad to obtain an illegal organ transplantation. Similar provisions should be made in national legal frameworks for other human material. Recognising that organ trafficking often involves “the poorer parts of the world”, mechanisms for traceability of organs entering the EU need to be put in place (something which has now happened). The resolution asks the Commission to raise the awareness of the issue of organ and tissue trafficking in its relations with third countries.

At a transnational law enforcement level the European Parliament resolution called for a common approach within the Area of Freedom, Security and Justice, a compilation of “information on national organ trafficking legislation and to identify the main problems and potential solutions” to this crime. In addition both law enforcement agencies and medical staff should be trained in order to assist in combatting this crime area. The proposed EU’s Action Plan on Trafficking in Human Beings was to include organ trafficking “in order to enable closer cooperation among the authorities concerned”.

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132 Organ donation and transplantation: Policy actions at EU level, European Parliament resolution of 22 April 2008 on organ donation and transplantation: Policy actions at EU level (2007/2210 (IN1)).

133 Ibid., point B.

134 Ibid., point 56.

135 Ibid., point 53.

136 Ibid., point 54.

137 Ibid., point 51.

138 Ibid., point 50.

139 Ibid., point 52.

140 Ibid., point 55.

141 Ibid., point 58.
Europol to be asked to improve “monitoring of cases of organ trafficking and to draw the necessary conclusions”\(^\text{142}\). Other human material relevant to OTC trafficking seems to have been missed in this action plan. Although Europol is very active in THB, it is not clear that it has begun to directly address the issue of organ trafficking or indeed OTC trafficking. While organ trafficking does feature in Directive 2011/36/EU on combating THB\(^\text{143}\), the other aspects of OTC trafficking are missing. In addition, no specific provisions addressed either organ trafficking, or THB for the purposes of organ removal, let alone tissues and cells in the EU Strategy towards the Eradication of Trafficking in Human Beings 2012–2016\(^\text{144}\), the 2017 follow up document on identifying further concrete actions to combat THB\(^\text{145}\) or even the most recent EU Strategy on Combatting Trafficking in Human Beings 2021–2025\(^\text{146}\). This area needs to be prioritized for resources to be allocated to combat this trade.

**UK**

While the UK has now left the EU, it is worth examining the approach it has taken to address the above issues, particularly as post-Brexit UK legislation still requires compliance with several EU provisions. The key English & Wales legislation on THB and related offences, the Modern Slavery Act 2015 provides that the term “exploitation” for the purposes of the section 2 offence of THB is to include where a “person is encouraged, required or expected to do anything” which would involve the commission of an offence under sections 32 or 33 of the Human Tissue Act 2004, which applies differently in England, Wales and Northern Ireland, as it has effect in England & Wales. Section 32 provides

\(^{142}\) Ibid., point 57.


\(^{146}\) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the EU Strategy on Combatting Trafficking in Human Beings 2021 – 2025, COM (2021) 171 final.
a prohibition of commercial dealings in human material for transplantation, which could lead to imprisonment for up to three years. This is replicated in the Scottish legislation. Section 33 of the Human Tissue Act deals with restriction on transplants involving a live donor, a general prohibition, from which limited exemptions can be permitted by regulation, breach of which can lead to imprisonment for up to 51 weeks. Identical provisions are in place for Scotland and Northern Ireland in their respective legislation. The Human Tissue (Scotland) Act 2006, as amended, for its part, provides that the removal or use of part of a deceased person for transplantation, research etc., without authorisation, can lead to imprisonment for up to three years. Not covered by the Human Tissue Act 2004 is reproductive material or “material which is the subject of property because of an application of human skill”. This exception is missing from the Scottish act, with the Scottish legislation, therefore, covering a wider range of human tissue. Payment of expenses, or loss of earnings of the donor, is however permitted. In Scotland the Scottish Ministers “may provide assistance and support” to donors, “on such terms, including terms as to payment, as the Scottish Ministers think fit”. The UK jurisdictions therefore deal in one legal framework with what is seen at a global level as the distinct crimes of THB for organ removal and OTC trafficking.

The Human Tissue Act 2004, at section 32, continues to make express reference to, and the need to comply with Directive 2004/23/EC on human tissues and cells, and (incorrectly numbered) EU Directive 2010/45/EU (in the UK legislation 2010/53/EU) on human organs, post-Brexit. The Scottish act, at section 55, gives power to the Scottish Ministers to give effect to EU obligations in this area, even post-Brexit, with section 19 providing that the Scottish Ministers may issue regulations covering the need for records, with non-compliance with provisions leading to a criminal offence to be pursued by way of a summary conviction. Since 2022 both the Human Tissue Act 2004 (section 32A extending the reach of section 32, for England and Wales), and the

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147 Human Tissue (Scotland) Act 2006, section 20.
148 Human Trafficking and Exploitation (Scotland) Act 2015 asp 12 (Scottish Act), Section 3.6, with reference to Part I of the Human Tissue (Scotland) Act 2006.
150 Human Tissue (Scotland) Act 2006, section 16.
151 Human Tissue Act 2004, section 32.9.
152 Ibid., section 32.7.
153 Human Tissue (Scotland) Act 2006, section 2.
Human Tissue (Scotland) Act 2006 (section 20A extending the reach of section 20) have acquired extraterritorial reach for their “prohibition of commercial dealings in human material for transplantation” offences. Extraterritorial reach of relevant domestic legislation in this area would appear to be key in combating organised crime’s supply of human material in global supply chains.

All parts of the UK are subject to the operation of the UK’s Human Tissue Authority (HTA),156 which regulates the use of bodies of deceased, or the use or storage of “relevant material which has come from a human body”. It operates with input from a representative appointed by the Scottish Ministers.157 The HTA has issued several codes of practices to cover dealings with human bodies and tissues in a variety of situations. The HTA was the designated “competent body” in the UK for meeting the requirements of the EU’s organ directive, 2010/45/EU,158 and continues in that role post Brexit. The HTA’s Code of Practice; A Guiding Principles and the Fundamental Principle of Consent159 provides that dealings with human bodies and tissues should be governed by four overriding principles; consent, dignity, quality and honesty and openness.160 Anyone dealing with human tissue “must be satisfied that consent is in place.”161 For consent to be considered valid it “must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question”.162 An approach taken in many countries, but not in the UK, is, in the case of live donors, the requirement for “psychological and psychosocial evaluation of donors” in order to insure, inter alia, “an absence of ambivalence or pressure to donate”.163 The absence of this in the UK system might be a weakness in addressing the issue of forced organ or tissue removal.

All four UK jurisdictions have now adopted a presumed consent for deceased tissue donations.164 Exceptions are made for children and adults who lack

157 Ibid., Schedule 2, 1.3.
160 Ibid., p. 8.
161 Ibid., p. 13.
162 Ibid., p. 15.
capacity to consent. It is also possible to opt out from the presumed consent provisions. Differences in approaches can be seen in adopting presumed consent for dealing for these exceptions, and for those who have opted out of the presumed consent provisions. There are therefore still situations where it continues to be an offence to deal with human organs, tissues, or cells without consent after death, in addition to removal from live donors. For example, it is an offence under Scottish law to remove from a live donor who is a child or a person with incapacity, tissue, organs, or parts of organs. This could lead to imprisonment not exceeding 12 months.\footnote{165 Human Tissue (Scotland) Act 2006, section 17.} For donations by children after their death under Scottish law a distinction is made between children under the age of 12, and children over the age of 12. In line with the UN Convention on the Rights of the Child, 1989, Article 12, children over the age of 12 years are capable of authorising removal of part of their body after their death.\footnote{166 Ibid., section 8.} Under the Scottish law children who die under the age of 12 years, authorisation to remove parts of the child’s body must be made by that person who had “parental rights and responsibilities in relation to a child”, but the views of the recent views of the child under 12 on the issue must be respected.\footnote{167 Ibid., section 10.}

**Conclusion**

There are very close connections between THB for organ removal, meeting the action, means and purposes tests, and the larger volume trafficking of OTC. While there are transnational legislative provisions to combat THB for organ removal, to include in the Palermo Protocol, there are legislative gaps for OTC at various levels, to include the lack of an internationally agreed definition for OTC.\footnote{168 Joint Council of Europe/ United Nations Study, op. cit., p. 12.} Both crimes need to be adequately addressed, with transnational law enforcement focusing on the most exploitative examples of these. The question arises how OTC recipient countries address these issues extraterritorially, to be able to effectively combat exploitation and the role of organised crime in human material transnational supply chains.

There is a lack of hard law addressing the issue of transplant tourism, with the medically derived DoI, and the WHA resolution\footnote{169 World Health Assembly Resolution 57.18, op. cit.} attempting to fill the gap. UN efforts on both organ and OTC trafficking have so far failed. The
medical professions have been asking for this matter to be addressed, however, for effective transnational legal frameworks, national laws will need to have extra-territorial effect. Opportunities to adopt an OTC reporting mechanism, informing transnational law enforcement, along the lines of the FATF mechanism used to combat money laundering, have therefore been missed.

At a CoE level both the European Convention of Human Rights and Biomedicine (Oviedo) 1997\(^\text{170}\) and the CoE Convention against Trafficking in Human Organs, 2015 (the Santiago Convention)\(^\text{171}\) have been enacted, with one of the purposes of the Santiago Convention being to combat the transnational crime of organ trafficking. Covered are the important issues of extra-territorial effect of its provisions, and transnational cooperation in investigating and prosecuting this crime. The broader issue of tissue and cell trafficking still eludes the CoE. Further work at the CoE level needs to be done on this issue.

The EU, along with legislating to combat trafficking in human beings for organ removal\(^\text{172}\) has legislated for state-to-state exchange of organs\(^\text{173}\), blood,\(^\text{174}\) tissue and cells.\(^\text{175}\) They also have adopted the Single European Code for tissues and cells, ensuring full traceability of all materials transplanted within the EU. Trafficking is acknowledged in the EU organ transplant legal framework, but not the tissue and cells provisions. These gaps need to be addressed, and the EU’s extensive provisions on transnational law enforcement fully engaged in combatting the role of transnational organised crime in the exploitative and illegal supply of OTC. At a UK level, the Human Tissue Act 2004, for England, Wales, and Northern Ireland, together with the Human Tissue (Scotland) Act 2006, do criminalise commercial dealings in the much broader concept of “human material” for transplantation. Both these acts have, from 2022, extraterritorial reach for their “prohibition of commercial dealings in human material for transplantation” offences.

The gaps in the current legislative provisions at each of the above levels needs to be addressed. In addition, the international medical profession is clearly asking for full engagement with transnational law enforcement to combat the reality of the situations that responsible members of the medical profession are encountering in practice. There is a need for high level law enforcement to formally engage with medical authorities to develop working methods and

\(^{170}\) Oviedo Convention, op. cit.
\(^{171}\) Santiago Convention op. cit.
\(^{172}\) Directive 2011/36/EU, op. cit.
practice manuals to be able to address what is likely to be an increasing area of victim vulnerability and exploitation in the future. The EU and the UK are the best placed legal jurisdictions to develop, possibly jointly, the necessary comprehensive legal frameworks, practice manuals and working methods to combat the role of transnational organised crime in the illegal supply of OTC.