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Regulating Organ Donation and Transplantation under European Union Law: A Success Story?

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1. Introduction

Although the regulation of national organ donation and transplantation schemes remains under the exclusive competence of European Union (EU) Member States, the influence of EU law and policy cannot be ignored. Directive 2010/53/EU (the 'Organ Directive') is a clear example of EU intervention in the field of organ donation and transplantation, setting safety and quality requirements applicable in all 28 Member States.[1] In addition, complementary regulatory and policy tools have been developed to facilitate and enhance transplantation practices in Europe. A key question is how EU transplantation law and policy have contributed to improving the fundamental right of access to healthcare and, more specifically, enhancing equal access to organ donation and transplantation services in the EU.

To answer this question, this article will explain the role of the European Union focusing on the EU legal and policy framework on organ transplantation and assess its successes and shortcomings with an analysis of several key aspects of the equal access concept as understood from a human rights perspective. Finally, the unsolved issues in EU organ donation and transplantation law to be solved in strengthening citizens' right to healthcare will be provided.

2. Background: Facts and Figures

Every second Saturday in October, we celebrate the European day for organ donation and transplantation to honour all organ donors and thank transplant professionals throughout Europe. Unfortunately, transplant waiting lists are longer than ever before. In 2014, more than 70,000 people in the EU were still on transplant waiting lists, making the lack of organs the main

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1 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on the standards of quality and safety of human organs intended for transplantation [2010] OJEU L207/14, 6 August 2010; see Corrigendum to Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 [2010] OJEU L243/68, which makes it clear that the correct number is Directive 2010/53/EU.

obstacle to organ transplantation. In 2014, 12 people died every day because of the lack of available organs.[2]

In the EU, each Member State is responsible for the organisation of the transplant system, which differs from one country to the other. Irrespective of the organisational model, their commonality is the underlying principle of the donor´s consent prior to donation. Roughly speaking, there are two consent systems for obtaining organs: the so-called explicit consent of donors or relatives ('opting-in'), and the presumed consent system for donation ('opting-out'). In practice, however, a combination of both options is also possible, where the opinion of the next-of-kin is asked and respected (in the case of opting-out). Most EU Member States have an opting-out system.[3] In terms of outcomes, it appears that in general, the latter leads to a higher number of (deceased) organs transplanted.[4]

Although most organs purchased are derived from deceased donor transplant procedures, living donation (kidney, liver) programmes with (un)related donors exist in virtually all countries.[5] In order to protect living donors, organ trafficking is prohibited by law in most Member States.[6] Within deceased donation, most countries apply the brain death criterion (donation after brain death, DBD) while others use the donation after circulatory death (CDC), formerly non-heart beating criterion for organ transplantation.[7]

Most Member States collaborate in the exchange of organs and participate in European Organ Exchanges Organisations (EOEOs), such as Eurotransplant, Scandiatransplant, South Transplant Alliance, and/or have concluded several bilateral and multilateral exchange agreements primarily with neighbouring countries. The main reasons for such cross-border exchanges are to reduce the loss of donor organs for which there is no suitable recipient on the national

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2 Figures extracted from the Council of Europe/ONT annual newsletters: *Newsletter Transplant* 2015, 4-14; 64,000 in 2013 (Newsletter 2013); 61,500 in 2011 (Newsletter 2011) and from websites (Eurotransplant, Scandiatransplant, Southern Eastern Transplant Alliance, etc.): www.edqm.eu.en/organ-transplantation-reports-73.html.

3 Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015), known as: ACTOR study, June 2013.

4 L. Shepherd, R. O'Carroll & E. Ferguson, 'An International Comparison of Deceased and Living Organ Donation/Transplant Rates in Opt-in and Opt-out Systems: A Panel Study', *BMC Medicine* 12 (2014): 131. Traditionally, Spain and Croatia show a relatively high rate of organs transplanted (opting out), more recently, under the new Welsh 'deemed consent' system (2016), the first six-month results reveal an higher donor rate than under the previous opting-in scheme, source www.theguardian.com/society/2016/sep/04/welas-deemed-consent-organ-donation-system-promising-results.

5 ACTOR study, at 203.

6 Ibid., see outcomes analysis by country, priority no. 7.

7 European Commission, Commission Staff Working Document on the mid-term review of the Action Plan on Organ Donation and Transplantation (2009-2015): Strengthening Cooperation between Member States, Brussels 25.4.2014, SWD(2014) 147 final, at 20.

waiting list and to raise the odds for specific patient groups (in particular urgent, children 0-5 years, difficult-to-treat patients) to receive a matching organ. Such international donor sharing is not restricted to EU Member States, but may also cover EEA countries (Norway, Iceland, Switzerland) and neighbouring countries (for example, Macedonia). Figures for cross-border transplants or 'transplant tourism' show an annual exchange rate varying from 20% (Eurotransplant).[8] These figures for border-crossing organs emphasise the need for protecting citizens' health and the harmonisation of adequate regulatory instruments applicable throughout the entire Union. But what exactly is the EU doing in the field of organ transplants?

3. EU Legal and Policy Framework

On 6 December 2007, the Council of the European Union adopted a Council Conclusion which recognised the need for cooperation in the field of organ donation and transplantation between Member States.[9] Such cooperation would focus on measures setting high standards of quality and safety of organs for transplantation. Additional EU action is required since all Member States are being confronted with shortages of organs, and thus the risk of organ trafficking, the need for increasing donation rates, as well as differences in organ transplantation quality and safety rules, causing potential health risks for citizens.

The Council invited the European Commission to propose more specific measures to increase the availability of donor organs and formulate a common legal framework on quality and safety of organ transplantation. Subsequently, the Commission developed a framework called the 'Action Plan on Organ Donation and Transplantation 2009-2015: Strengthened Cooperation between Member States', which was adopted at the end of 2008.[10]

The former public health provision, Article 152(4) of the Maastricht Treaty (currently, Article 168 TFEU) functioned as the legal basis for this policy plan, reading:

'The Council (...) shall contribute to the achievement of the objectives referred to in this Article through adopting: (a) measures setting high standards of

8 European Commission, Journalist workshop on Organ donation and transplantation. Recent Facts and Figures, 26 November 2014 Brussels, Scandiatransplant show a range of 10-27% exchange of various organs (2013).

9 The Council of the European Union, Council Conclusions on Organ Donation and Transplantation 15332/07, 6 December 2007.

10 European Commission, Communication from the Commission. Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States, COM(2008) 819/3, Brussels, 8 December 2008.

quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures'.

Such safety measures remain complementary to national policies on organ donation (Art. 168[7]), and complement more general Union initiatives ensuring 'a high level of health protection'. This means that Union actions are aimed at:

'improving public health, preventing physical and mental illness and diseases, and obviating sources of danger of physical and mental health. Such action shall cover the fight against major scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health' (Art. 168[1]).

Articles 168 (1) and (4) TFEU are therefore the point of reference for any Union action in the field of organ donation and transplantation, as will be explained below in more detail. These actions, however, are not exclusively limited to EU Member States, but may also address neighbouring countries and relevant international organisations such as the World Health Organization (WHO). As the TFEU stipulates: 'the Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health' (Art. 168[3]).

With the Treaty of Lisbon, the Charter of Fundamental Rights of the European Union came into force and became legally binding for EU institutions and Member States when implementing EU law, protecting the rights of citizens. The Charter defines basic standards to be respected in all areas, including the field of organ donation and transplantation, such as the rights to: dignity;[11] integrity;[12] private life;[13] protection of personal data;[14] non-discrimination;[15] and the right to healthcare.[16] These rights create numerous human rights obligations within the scope of organ donation and transplantation. For instance, the prohibition on commodifying human organs; consent is the underlying principle of organ donation; protecting the confidentiality of medical data of organ donors and recipients; providing access to transplantation services of sound quality; and respecting the non-discrimination principle, meaning the allocation of or-

11 Art. 1.
12 Art. 3.
13 Art. 7.
14 Art. 8.
15 Art. 21.
16 Art. 35.

gans based on medical and medically-related criteria only. Most of these rights are protected under the 'Organ Directive'.

In the Action Plan on Organ Donation and Transplantation,[17] the Commission sets out an ambitious three-layer framework. Each of the layers covers a detailed list of priority actions, supported by the Commission. Based on national needs and specific circumstances, each Member State will decide what kind of action is required to meet the common objectives:

i. increasing organ availability by improving the identification of potential donors; appointment of transplant donor coordinators, allowing living donation complementary to deceased donation, and investing in public awareness campaigns providing information about donation and transplantation;
ii. enhancing the efficiency and accessibility of transplantation systems. Comparing the outcomes of transplantation systems requires a set of common indicators to monitor organ policy (requirements for donation, transplantation, etc.), and a methodology to evaluate the potential in each country. The assessment of good practices could be a useful tool for other Member States. Secondly, increasing the exchange of organs between Member States will improve the prospects of certain categories of patients, e.g. urgent and 'difficult to treat' patients, especially in small countries. Finally, establishing an EU-wide agreement on monitoring organ trafficking as it undermines equal access to scarce organs and violates human rights.
iii. improving quality and safety. Given the potential health risks in cases of cross-border flows of organs (transmission of HIV, hepatitis B and C, etc.), and the diversity of rules regulating the safety and quality standards on organ donation and transplantation, there is a clear need for setting minimum standards. Directive 2010/53/EU is the key legal document defining these standards based on the Union public health mandate.

As part of the Action Plan, Directive 2010/53/EU (rectifying Directive 2010/45/EU), is the most explicit legal tool helping to 'reassure the public that organs procured in another Member State carry the same basic quality and safety guarantees as those obtained in their own country',[18] and at the same time maximising the benefits of transplantation by establishing 'a framework encompassing the entire chain from donation to transplantation, and covering the healthcare personnel and organisation, equipment, materials and record-keeping involved'.[19] These objectives directly refer to the public health rationale underlying Art. 168 TFEU: ensuring a high level of human health protection. Key elements of the Directive's quality and safety framework are mentioned in

17 Action Plan (*supra* note 10), at 2-8.
18 Recital 6 Directive 2010/53/EU.
19 Ibid., recital 9.

Art. 4, including the verification of donor identity, verification of donor's (family) consent, organ procurement, transportation of organs, ensuring traceability, reporting and management of serious adverse events. These elements are developed in more detail in the following provisions, and had to be implemented into national law by 27 August 2012. The organisational, managerial and procedural requirements formulated by the Directive – including the implementing Directive[20] – set the basic conditions for national transplantation centres. At the same time, the Directive stipulates that healthcare personnel involved should be 'suitably qualified and trained', and that 'the medical activities, such as donor selection, are performed under the guidance of a doctor of medicine', as referred by the Directive on the recognition of professional qualifications (Directive 2005/36/EC). These requirements illustrate the limited meaning of the supremacy of national policies (Art. 168[7]) in the field of organ donation and transplantation.

This is different with respect to the donor consent system ('opting-out' or 'opting in'). Here, the Directive is neutral and leaves it up to individual Member States what kind of consent is required (explicit or presumed, or even something in between). This approach also applies to another issue: deceased or living donation. Both modalities are left open, following the Council of Europe approach in the Biomedicine Convention.[21]

Of further relevance is the consensus on principles governing organ donation: voluntary and unpaid donation; leaving room for a modest compensation of certain expenses in the case of living donation; a ban on organ-advertising and organ trafficking; the non-profit nature of organ procurement; and the protection of personal data in all organ donation and transplantation activities (Ch. III). These EU-wide accepted principles reflect a wide notion of quality, not restricted to medical-technical aspects of organ donation and transplantation but also including ethical-legal issues. As such, these principles set further obligations for Member States such as assigning a competent authority responsible for the quality and safety framework, supervising organ procurement organisations and transplantation centres (for example, licensing), and the exchange of organs, developing a 'track-and-trace' system for organs, establishing a reporting system for serious adverse events, effectively protecting personal data, etc. At EU level, the European Commission is responsible for establishing a network

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20 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, OJUE L 275/27, 10 October 2012.

21 Officially known as 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. ETS No. 164, 4 April 1997. For an extensive analysis of the Biomedicine Convention and the Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, ETS no. 186, 24 January 2002, see R. Andorno, 'Buying and Selling Organs: Issues of Commodification, Exploitation and Human Dignity', in this Journal.

of competent authorities exchanging information on 'best practices' implementing the Directive (Art. 19).

In order to increase the availability of organs and enhance the efficiency of transplant systems, bilateral agreements with third countries can be concluded on the exchange of organs.[22] Such agreements are, however, strictly regulated under the Directive in order to prevent the spread of potential health risks, and to endure the traceability of the donor or recipient. Moreover, such agreements should respect the principle of self-sufficiency in transplantation.[23]

4. Analysis: (Un)solved Issues

Exploring the EU framework in terms of accessibility of transplant services, the key question is: has it contributed to an increase in available organs for transplantation? As this was the rationale, or at least one of the reasons, for adopting the Directive and the underlying Action Plan. Secondly, how did EU law and policy improve the quality and safety of organ donation and transplantation? These are two rather simple questions that are unfortunately not so easy to answer since it requires more than a literature review as the basis for the writing of this contribution. Despite the methodological limitations, these questions will be explored in more detail below.

From a human rights perspective, one might argue that the EU-wide policy and regulatory measures reflect the notion of taking progressive steps and ensuring compliance with the state obligations as interpreted in the General Comment no. 14 on the Right to Health, hereafter GC14.[24] This authoritative document provides further guidance on how to comply with the right to health, as accepted under national law and the EU Charter of Fundamental Rights. For instance, individual Member States – as well as international organisations such as the EU – have 'the immediate obligation to take steps towards 'the full realisation of such a right', and to guarantee this without discrimination. Moreover, such steps must be deliberate, concrete and targeted towards the full realisation of the right to health.[25] Having a direct effect, these obligations should be fulfilled immediately, whereas the progressive realisation of that right means that Member States 'have a specific and continuing obligation to move

22 In 2015, the Commission decided to support such initiatives by funding a 'platform for increasing organ donation in the EU and neighbouring countries' on an experimental basis, Commission Decision, 10 July 2015 C(2015) 4583 final.

23 Madrid Resolution on Organ Donation and Transplantation, National responsibilities in meeting the needs of patients, guided by the WHO principles, *Transplantation* (2011): 91 (S29-31).

24 Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), E/C.12/2000/4.

25 GC14, para. 30.

expeditiously and effectively as possible towards the full realisation' of the right to health.[26] Secondly, like all human rights, the right to health imposes three types of obligations on states: to respect, protect and fulfil, that is, states should refrain from interfering with the enjoyment of the right to health, should take measures to prevent third parties from interfering, and should adopt appropriate measures towards the full realisation of the right to health.[27] Following this interpretation, one may conclude that the Action Plan on Organ Donation and Transplantation, and the 'Organ Directive' as implemented in national law and policy, reflect the first step towards an increase of available donors and transplantations, a key element of the full realisation of the right to health. The Action Plan and regulatory steps taken are aimed at ensuring compliance with the General Comment's obligation to fulfil (that is, the legislative implementation plan). In addition Directive 2010/53/EU incorporates the human rights' obligations to respect and protect by abstaining from discriminatory practices to make sure organs are transplanted based on objective medical criteria only,[28] by controlling organ procurement organisations and transplant centres,[29] and by ensuring that medical personnel involved meet professional standards.[30] Simultaneously, the Directive has recognised that access to high quality donor and transplantation services is dependent on and related to other human rights, such as informed consent, confidentiality and privacy, aimed at protecting the donor and recipient.[31] All of these human rights requirements have to be incorporated in national law (Art. 31).

As shown by Sheppard et al., the opting-out consent model reveals the highest number of donated organs (deceased donation).[32] This means that under the 'availability' condition of the right to health, this model should be promoted instead of opting-in.[33] Still, the consent system remains under the discretionary freedom of individual Member States (Art. 14). This can be explained taking into account the 'acceptability' condition: all health goods and services provided must be respectful of medical ethics and culturally appropriate, that is, respectful

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26 Ibid. para. 31.

27 Ibid. para. 33.

28 Recital 20 Directive 2010/53/EU: 'allocation of organs based on transparent, non-discriminatory and scientific criteria'.

29 Art. 17(2)(b) Directive 2010/53/EU.

30 Art. 4(3) Directive 2010/53/EU.

31 Confirmed by Ch. III on 'the principles governing organ', consent requirements, data protection and confidentiality', Arts. 13-16 Directive 2010/53 EU.

32 Shepherd, O'Carroll & Ferguson, *supra* note 4. Although some experts now believe that increased organ donation rates are more closely associated with systemic changes in healthcare systems that facilitate early identification of potential organ donors than the consent model: J. Fabre et al., 'Presumed Consent Is Unnecessary', *BMJ* 341 (2010): 922-924. Indeed, changing the legal model in itself will not be a guarantee for an increase in donation rates.

33 The right to health depends on several conditions: availability, accessibility, acceptability and quality of health facilities and services (the so-called AAAQ framework), GC14 para. 12 (c).

of the culture of individuals and communities. Due to the lack of consensus on the medical ethical 'appropriateness' of the opting-out model at European level, the choice of model is left open under the Directive.

On the other hand, under the Charter's right to healthcare (Art. 35), and other fundamental rights, such as the right to life (Art. 2), the prohibition of inhuman or degrading treatment (Art. 4), private life (Art. 7), and non-discrimination (Art. 21), one may argue that these rights require Member States to take all necessary steps to increase the rate of available donors, including adjustment of the consent model. This can be based on the European Court of Human Rights, which has generally accepted the idea of both negative and positive obligations under the European Convention on Human Rights in health-related matters (for example, right to life, prohibition on inhuman and degrading treatment, and right to private life).[34] Here, the Court accepted an extensive interpretation of so-called 'negative' rights, meaning that, apart from refraining from unlawfully taking of life (Art. 2), the prohibition of ill-treatment (Art. 3), and respect for private life (Art. 8), the Convention's rights also impose a positive duty on the State to take reasonable and appropriate measures to secure the applicant's rights. Therefore, the failure to protect life by deliberately withholding or delaying medical treatment may result in a breach under the Convention, either under the right to life, the prohibition of inhuman and degrading treatment or under the protection of private life. So far, the Court of Justice of the EU has not confirmed this line of reasoning, despite the fact that Art. 52(3) of the Charter materially 'incorporates' the Convention.[35]

Finally, the quality condition has been generally accepted as another core element under the right to health, that is, health facilities, services and goods should be scientifically and medical appropriate and of good quality.[36] Under EU law, strengthening donation and transplant quality standards is aimed at setting *minimum* standards applicable throughout the entire Union, but this approach cannot hide that differences in quality standards still remain. Despite certain reservations concerning the 'flexibility' approach, what matters is that the implementation of EU quality norms on organ procurement and transport of organs into national law, indirectly enhances the effectiveness and efficiency of an EU-wide organ donation and transplant model. This has been confirmed

34 *Cyprus v. Turkey*, Appl. no. 25781/94, para. 219; *D v. United Kingdom*, Appl. no. 30240/96, paras 49-54; *Tysiac v. Poland*, Appl. no. 5410/03, para. 110; and confirmed in a most recent case, see *Otgon v. Moldova*, Appl. no 22743/07, para. 15.

35 Art. 52(3) reads: 'in so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention (...)'.

36 GC14, para. 12 (d).

by several joint projects, such as Foedus,[37] COORENOR[38] and ACCORD joint actions,[39] strengthening the legal and organisational set-up of national transplant systems, and the cross-border exchange. Based on this literature review, one may conclude that the regulatory and policy steps taken both at EU and Member State level reflect the core content of the right to health notion as accepted under international human rights law. Ultimately, these steps are the main driver for an increase of available organs of sound quality for patients in need.

At the same time, the Commission's mid-term review (2009-2012) revealed several issues that need further action at EU and Member State level.[40] For instance, to cope with the scarcity of organs, most Member States show an increase in living donations, while ensuring the protection of the living donor (voluntary and altruistic, non-remunerated donation as laid down in the Directive).[41] For this reason, Member States have to introduce a register or record capturing the long-term follow-up of these donors (Art. 15), while respecting donors and recipients' privacy and confidentiality in all donation and transplantation activities. Though the principle of voluntary and unpaid donation is generally accepted, not all 28 Member States have developed such a record as imposed by the Directive. Consequently, life-long monitoring of the living donor (serious adverse events resulting from donation) is absent or follow-up is limited in time.[42]

Another issue not covered by the Organ Directive is the following question: what happens when EU patients on the waiting list return with a donor organ from an 'unverifiable' source outside the EU? Is this something the Directive should deal with? Moreover, how should transplant professionals act when they receive a patient who bought a kidney from a living donor outside the legal scheme, for example in India? Should they disclose this information to national authorities (law enforcement) and breach the oath of secrecy? As the Directive's jurisdiction is limited to EU Member States only, living donors from a third country cannot be traced.[43] The Directive, therefore, cannot solve the phenomenon of organ trafficking *outside* the EU.[44] Instead, it is left open to transplant

37 Establishing an IT platform for European national transplant organisations to transmit information on the exchange of organs: www.foedus-ja.eu.

38 Establishing an online coordinated network on national organ donation and transplantation programmes: www.coorenor.ders.cz.

39 Aimed at increasing the cooperation on living donation: www.accord-ja.eu.

40 European Commission, Commission Staff Working Document, *supra* note 7, at 30-31.

41 Ibid. The number of organ transplants show an overall increase by 8% from 2007-2012 due to a number of factors, at 14-15, 30.

42 K. van Assche et al., 'The Relevance of Directive 2013/53/EU for Living Organ Donation Practice: An ELPAT View', *Transplantation* 10 (2015): 2215-2222, at 2218. Only 40% of Eastern European transplant centres offer follow-up to living donors.

43 Although some neighbouring countries have also aligned their actions with the EU approach (e.g., Switzerland, Iceland and Norway, etc.).

44 The only solution is that countries become self-sufficient in organ donation, in line with the Madrid Resolution on Organ Donation and Transplantation, 2010.

professionals how to act when confronted with a conflict of duties. It has been suggested that they should disclose information on organ trafficking networks to law enforcement authorities.[45] I will argue against it though. Securing access to transplant care, as part of the right to healthcare, prevents the physician from breaching the obligation of secrecy, even when he is confident the patient committed a crime (organ trafficking)! And even if the patient does inform him that he *will* buy an organ abroad, there is no professional obligation to report the patient to the police, unless the physician is confident that a breach of confidentiality will prevent any harm to the donor's health. But since the donor is unknown, disclosure of such information will be unlikely to protect the donor, and is therefore unjustified.

What has been solved is the risk of 'double or multiple listing' whereby a patient appears simultaneously on a waiting list in more than one exchange organisation in order to shorten his waiting time for an organ. This is because the Organ Directive facilitates organ transplant mobility in the EU. According to EOEO agreements, this phenomenon has been excluded as the allocation is governed by the principles of urgency and equity.[46] Double listing is only accepted for exceptional clinical reasons.

Complications may arise when patients are using social media and other creative ways of finding a living donor, an issue not covered by the Directive but not unlikely.[47] As Facebook can be a powerful network when it comes to addressing the organ shortage, receiving a donor from a Facebook friend, therefore circumventing the waiting list, has been generally considered as unjust. Still, procurement criteria for living donation may differ among EU Member States (relatives or non-genetically related persons), and therefore social media searches may also be valued differently. Although social media can have a positive effect (raising awareness and increasing donor rate), the allocation of organs should be based on medical criteria only.

What remains is 'the need for a common accreditation system' for organ donation, procurement and transplantation programmes. Based on Art. 17(2) of the Directive, national competent authorities will ensure an accreditation and auditing system for both donation and transplantation centres as part of the quality and safety framework. The Commission's review confirmed the action taken by Member States in this field, but also revealed that only 17 out of 27 Member States have accreditation systems in place (2014), whereas the quality criteria and indicators for accreditation and certification differ from one country

45 F. Ambagtsheer et al., 'Reporting Organ Trafficking Networks: A Survey-Based Plea to Breach the Secrecy Oath', *American Journal of Transplantation* 7 (2015): 1759-67.

46 Annual report Eurotransplant 2014, at 27 www.eurotransplant.org search for annual reports.

47 As mentioned by B. Duerr, 'Should Patients be able to find Organ Donors on Facebook?', *The Atlantic*, 15 April 2015 www.theatlantic.com, search for Facebook donor.

to the other.[48] The Council Conclusions 2012 already urged the need for Member States to 'share national procedures for authorisation of procurement organisations and transplantation centres', which will help those countries developing an accreditation system, as well as improving existing accreditation systems based on pan-European quality and safety standards.[49] In order to prevent any duplications, lessons can probably be drawn from the Council of Europe's work.[50]

5. Conclusions

Although the Organ Directive states that 'trafficking in organs constitutes (...) a serious violation of fundamental rights',[51] it is doubtful whether the measures taken – harmonising the activities of organ procurement and transplantation centres, developing a track-and-trace system for living donors, exchanging information between competent authorities, etc. – will prevent EU citizens from searching for an organ from an 'unverifiable' source outside the EU.

But that was not the main driver for the Directive. Challenged by the diversity of organ procurement, donation and transplantation norms and activities, its primary aim was to set minimum quality and safety standards, and thus protect the health of both donors and recipients. Given the outcomes in terms of the increased number of available organs, facilitating the European exchange of donor organs, the harmonisation of organ procurement, donation and transplantation practices, and the demonstrated exchange of information between competent authorities, it seems justified to conclude that the Directive, and the underlying Action Plan, despite its limitations, have been quite successful. Furthermore, they have contributed to the progressive realisation of the right to healthcare, addressing the AAAQ framework and specifying the obligations

48 European Commission, Commission Staff Working Document, *supra* note 7, at 64-66.

49 Council Conclusions on Organ Donation and Transplantation, para. 9.1, OJEU C 396/12, 21 December 2012.

50 E.g., Recommendations of the Council of Ministers: Rec(2004)19 on criteria for the authorisation of organ transplantation facilities, 15 December 2004; Rec(2006)16 on the quality of improvement programmes for organ donation, 8 November 2006; Rec(2006)15 on the background, functions, and responsibilities of National Transplant Organisations (NTO), 8 November 2006; and the CoE's Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, ETS no. 186, 24 January 2002.

51 Recital 7 Directive 2010/53/EU, full citation reading: 'Unacceptable practices in organ donation and transplantion include trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs, which constitutes a serious violation of fundamental rights, and, in particular, of human dignity and physical integrity'.

of Member States (to respect, protect and fulfil). Nonetheless, further steps still have to be taken that focus on the unsolved issues as outlined above.