



Council of Europe Black Sea Area Project: International Cooperation for the Development of Activities Related to Donation and Transplantation of Organs in the Region

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ABSTRACT

Background. In 2011, the European Directorate for the Quality of Medicines & Healthcare of the Council of Europe launched a 3-year collaborative project to address the organ shortage and improve access to transplant health services in Council of Europe member states in the Black Sea area (Armenia, Azerbaijan, Bulgaria, Georgia, Moldova, Romania, Turkey, Ukraine, and the Russian Federation) through the development of safe and ethical donation and transplantation programs.

Objective. Support the development of donation and transplantation programs through close interstate cooperation between national health organizations and relevant stakeholders.

Methodology. Several work packages (WP) were established: WP1, project coordination (European Directorate for the Quality of Medicines & Healthcare); WP2, development and implementation of an effective legislative and financial framework (Czech Republic and France); WP3, establishment of National Transplant Authorities (Italy and Portugal); and WP4, clinical practices (DTI Foundation). Data collection, surveys, and expert visits allowed for the collection of first-hand information from each participant country at national, regional, and hospital levels.

Results. Data analysis showed the positive impact of the project represented by a tendency to increase the total donation rates (per million people) in the participant countries (2011 vs 2013): Azerbaijan, +7.3; Armenia, -0.7; Georgia, +3.3; Bulgaria, +0.9; Moldova, +2.5; Ukraine, +0.8; Romania, +2.3; and Turkey, +2.7.

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Conclusions. Increases in total donation rates are the result of a number of initiatives in the Black Sea area, including the stepwise implementation of legislative, organizational and institutional country-specific recommendations tailored by the CoE, efforts of the respective Ministries of Health in each country and synergism with other European projects in the region. These countries should invest further in implementing the recommendations that emerged from this project to improve their organ donation and transplantation programs and progress toward self-sufficiency.

THE COUNCIL of Europe [1] (CoE) is an intergovernmental organization that covers, by virtue of its 47 member states, the entire European continent. Founded in 1949, the CoE promotes human rights, democracy, and the rule of law. The work of the CoE in the area of organ transplantation started in the 1980s. In particular, activities based on blood transfusion and organ transplantation are managed by the European Directorate for the Quality of Medicines & HealthCare (EDQM), a directorate of the CoE. The EDQM is a leading organization that protects public health by supporting the development, implementation, and application of quality standards for medicines and health care.

The European Committee on Organ Transplantation (CD-P-TO) is the steering committee in charge of organ transplantation activities at the EDQM [2]. It actively promotes the noncommercialization of organ donation [3], fight against organ trafficking [4,5], and the development of ethical, quality, and safety standards in the transplantation of organs, tissues, and cells [6]. Its activities include the collection of international data and monitoring of practices in Europe, transfer of knowledge and expertise between organizations and experts through training and networking, and elaboration of reports, surveys, and recommendations.

In recent years, the CoE and the World Health Organisation began to implement projects that supported the development of a common and constructive attitude toward transplantation issues in various countries [7,8]. Efforts were mainly directed toward the development of effective legislative frameworks and the establishment of national transplant organizations (NTOs) and transplant programs [9].

PREVIOUS ORGAN DONATION AND TRANSPLANTATION INITIATIVES IN THE BLACK SEA AREA

Development of organ transplantation activities in the countries of the Black Sea area (BSA) began in the late 1970s; however, they began to decline in the early 1990s, and, later ceased in some countries. Therefore, the identification and sharing of experiences from countries with well-developed and established transplantation programs and local initiatives has become vital [10]. Such activities could provide models for the implementation of safe donation and transplantation programs in BSA countries according to their state of development and cultural backgrounds [11].

In 2004, the CoE and the European Commission agreed on a joint program for the Republic of Moldova that

focused on transplantation services and combatting organ trafficking. As a result, a new law on transplantation was adopted by the Moldovan Parliament in 2008, and a transplant organization was established that is now responsible for all organizational aspects in this field. After the Moldovan experience, it became evident that experiences from countries with well-developed and established transplantation programs should be shared, and that local initiatives could provide models for increasing transplantation activity as well as for the implementation of safety and quality programs throughout Europe [12].

THE BSA PROJECT

In 2011, the CoE launched a 3-year collaborative project to counteract organ shortages and improve access to health services related to transplantation in the BSA member states (Armenia, Azerbaijan, Bulgaria, Georgia, Moldova, Romania, Turkey, Ukraine, and the Russian Federation) through the development of safe and ethical donation and transplantation programs. The BSA project was based on the philosophy that CoE member states with established and successful transplantation systems would transfer their knowledge and experience to BSA countries with the support of the CoE, who would provide political and logistical support to the project. Efforts were directed mainly toward the development of effective legislative frameworks and the establishment of NTOs as well as national transplant programs and infrastructures. Transplant specialists from members of the CD-P-TO, namely France, Italy, the Czech Republic, Portugal, and Spain, participated and supported experts from BSA countries.

OBJECTIVES

The main objective of the project was to support the development of organ donation and transplantation programs through close interstate cooperation between national health organizations and relevant stakeholders.

The specific objectives of the project were to (a) structure and enhance the exchange of knowledge between the partners of the project, (b) ensure transfer of best available expertise and good practices in the field of transplantation between CoE member states, (c) review existing laws on transplantation of organs, tissues, and cells, and promote implementation of an effective legislative framework, (d) contribute to the establishment of national transplant authorities and national transplant programs where these

structures did not exist and support efforts to strengthen existing transplant services, (e) educate the public, professionals, and the media about transplantation and the need for services to be developed in the countries involved in the project, (f) establish action plans for training and identify areas in which additional specialist expertise or training are required as a basis for a development strategy, (g) elaborate recommendations and consensus documents agreed upon by all participants, (h) encourage networking and enhance international cooperation, and (i) establish pilot actions to be developed in specific areas.

METHODS

The BSA project was organized as 4 work packages (WPs). They were focused on various aspects of the donation and transplantation processes based on the level of development of the existing transplantation activities in each BSA member state.

WP 1: Project Coordination

The EDQM/CoE was in charge of overall project management. A steering committee included international experts nominated by the CD-P-TO NTOs of countries with well-developed transplant programs and was organized to guide and ensure the successful development of the project.

WP 2: Development and Implementation of an Effective Legislative and Financial Framework for Transplantation Activities

WP2 (implemented in Armenia, Azerbaijan, and Georgia) was coordinated by the Agence de la Biomédecine (France) and Koordinační středisko transplantací (Czech Republic). Countries participating in this WP already had legislation on organ transplantation in place, but no established NTOs. There was some existing organ transplantation activity from living donation, but no deceased donation programs. This WP was focused on the assessment of existing transplant legislation, financial provisions in each country relative to health programs and transplantation activities, and the analysis of the political, institutional, and structural obstacles to the development of transplantation programs, with the aim of fostering political support to develop and maintain such programs.

WP 3: Establishment of National Transplant Authorities

WP3 (implemented in Bulgaria, Moldova, and Ukraine) was coordinated by the Centro Nazionale Trapianti (Italy) and the Autoridade para os Serviços de Sangue e da Transplantação (Portugal). This WP was focused on the establishment of national transplant authorities and on the evaluation of existing organizational systems and their functionality to identify areas for intervention and improvement and to establish adequate organization and coordination of the transplantation activities at a national level [13]. The 3 countries participating in this WP had established NTOs, and some of them had minimal deceased donation activity.

WP 4: Clinical Practices

WP4 (implemented in Romania, the Russian Federation, and Turkey) was focused on analyzing clinical practices for the donation-transplantation process within hospitals. This WP was coordinated by the DTI Foundation. Participating countries had

established NTOs and fully functional living and deceased donation programs, but donation rates remained low. Actions were focused on the evaluation of procedures and practices at the local hospital level to provide solutions for improvement [14].

Between December 2011 and March 2012, information about each BSA participant country was collected using several organ donation diagnosis questionnaires. The questionnaires evaluated the performance of each country at national, regional, transplant coordination and intensive care unit level. They also included information about transplantation programs and activity, as well as the organizational structure of donation at 4 levels: central, donation coordinators, donor hospitals, and organ sharing.

After analysis of the preliminary questionnaire results, site visits were performed in each participant country; these were essential for completing each country's evaluation. The objective of the in situ expert visits was to obtain first-hand information about the donation and transplantation of organs at national, regional, and hospital levels by detecting problems and proposing solutions [15]. Recommendations were then produced for each country based on the elaborated reports.

In June 2014, the development of each participant country in terms of legislation, organization, structure, and education was analyzed by EDQM/CoE experts. Organ donation and transplantation rates were analyzed and compared with figures from 2011. Although the Russian Federation initially planned to participate in this project, and some analyses were performed at the beginning of program, no site visits took place and they did not participate in data collection exercises during later stages of the project. This article does not, therefore, include data derived from the evaluation of this country.

RESULTS

Since the project was implemented in 2011, data analyses have shown a positive impact represented by a tendency for increased donation rates in almost all countries. The national focal point of each country was in charge of providing and validating the project results.

Analysis of Donation and Transplantation Organisation Activities

Table 1 summarizes the actions implemented by BSA participant countries to manage its NTO and their NTOs and donation activities. In 62.5% of analyzed BSA countries, a specific NTO was responsible for the national coordination of donation and transplant activities. In 75% of analyzed countries, a scientific institution was responsible for leading donation and transplantation activities; organizations operated at regional or local levels in the remaining 25%. All participant countries had established living donation programs, and the NTO was involved in living donation activities in 62.5% of these. National registry databases were implemented in 50% of analyzed countries, and national registries responsible for the lifelong follow-up of living donors were established in 37.5%. Additionally, 62.5% of participant BSA countries had established deceased donation programs. The NTO was involved in deceased donation programs in 50% of the analyzed countries, and national registries for deceased donation had been established in 50% participating countries. Fifty percent of BSA countries

Table 1. Comparison of National Organisation Activities, Legislative Aspects, and Educational Initiatives in BSA Participant Countries in 2014

	WP2			WP3			WP4	
	Armenia	Azerbaijan	Georgia	Bulgaria	Moldova	Ukraine	Romania	Turkey
Overview of the national organization								
Official NTO	No	No	No	Yes	Yes	Yes	Yes	Yes
Scientific organization responsible for leading of donation and transplantation activities	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Ethical committee dealing with transplantation activities nationally or regionally	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Regional or local organization dealing with transplantation activities	No	No	No	No	No	No	Yes	Yes
International agreements for organ sharing	No	No	No	Yes	N/A	N/A	Yes	Yes
Management of living donation								
The country has an established living donor program	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
NTO involved with living donation	Yes	Yes	Yes	Yes	Yes	No	No	No
National registry database for living donation	No	No	No	Yes	Yes	No	Yes	Yes
National registry includes lifelong follow-up for living donation	No	No	No	No	Yes	No	Yes	Yes
Management of deceased donation								
Country has an established deceased donation program	No	No	No	Yes	Yes	Yes	Yes	Yes
National transplant agency involved with deceased donation	No	No	No	Yes	Yes	No	Yes	Yes
National registry database for deceased donation	No	No	No	Yes	Yes	No	Yes	Yes
Donor coordinator is involved in the donation system	No	No	No	Yes	Yes	No	Yes	Yes
Legislative aspects								
Regulatory framework on the transplantation and donation of organs	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Regulatory framework of the death diagnosis	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Law concerning prohibition of organ trafficking	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
PC vs IC	PC	PC	IC	PC	PC	IC	IC	IC
Donor or nondonor registry legislations	No	No	Yes	Yes	Yes	No	No	Yes
Convention of Human Rights and Biomedicine*	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Additional Protocol of the Oviedo convention [†]	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Convention on Action against Trafficking in Human Beings [‡]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Initiatives to enhance educational programs								
Training programs to harmonize practices for staff involved in organ procurement	No	No	No	Yes	Yes	Yes	Yes	Yes
Training programs to harmonies practices for staff involved in organ transplantation	No	No	No	Yes	Yes	Yes	Yes	Yes
Continuous campaigns	No	No	No	Yes	Yes	Yes	No	Yes
Educational campaigns in schools or universities	No	No	No	Yes	No	No	No	Yes

Abbreviations: IC, informed consent; N/A, not available; PC, presumed consent.

*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. Source: <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>.

[†]Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin. Source: <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>.

[‡]Council of Europe Convention on Action Against Trafficking in Human Beings. Source: <http://conventions.coe.int/Treaty/en/Treaties/Html/197.htm>.

had a full- or part-time donor coordinator in some of their donor hospitals; some of these coordinators were appointed at a national level, others at the hospital level. The tasks and background of the donor coordinators differed in each country.

Analysis of Legislative Aspects and Initiatives to Enhance Educational Programs

In all BSA countries, governments promoted legislation to improve and optimize donation and transplantation activities. In 87.5% of BSA countries analyzed, legal criteria permitting organ donation after brain death had been established. In 50%, a donor or nondonor registry existed.

Fifty percent of BSA countries had adopted an informed consent system, and the remaining 50% had adopted a presumed consent system. In addition, 75% of the assessed BSA countries had signed both the CoE *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* (Oviedo Convention) [16] and the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin [17]. In addition, all analyzed BSA countries have signed the CoE Convention on Action Against Trafficking in Human Beings [4].

Table 2. Growth of Deceased Donation and Living Donation Rates in Black Sea Area Countries

Year	Organ	2011						2012						2013						Δ Total Donation (pmp) 2013–2011
		Living Donation		Deceased Donation		Total Donation		Living Donation		Deceased Donation		Total Donation		Living Donation		Deceased Donation		Total Donation		
		Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	Abs Number	pmp	
WP2																				
Armenia	Kidney	11	3.7	0	0	10	3.7	9	3.0	0	0	9	3	9	3.0	0	0	9	3	−0.7
	Liver	0	0	0	0			0	0	0	0			0	0	0	0			
Azerbaijan	Kidney	13	1.4	0	0	16	1.7	45	5.0	0	0	61	6.7	67	7.3	0	0	86	9	7.3
	Liver	3	1.3	0	0			16	1.8	0	0			19	2.0	0	0			
Georgia	Kidney	17	3.8	0	0	17	3.8	15	3.3	0	0	15	3.3	32	7.11	0	0	32	7.1	3.3
	Liver	0	0	0	0			0	0	0	0			0	0	0	0			
WP3																				
Bulgaria	Kidney	9	1.3	8	1.1	16	2.3	9	1.3	4	0.6	13	2.1	11	1.6	177	2.4	21	3.2	0.9
	Liver	3	0.4	3	0.4			2	0.3	0	0			0	0	7	1.0			
Moldova	Kidney	0	0	0	0	0	0	4	1.2	4	1.2	4	1.2	6	1.7	0	0	9	2.5	2.5
	Liver	0	0	0	0			0	0	0	0			3	0.9	0	0			
Ukraine	Kidney	62	1.4	2	0.5	103	2.3	115	2.6	4	0.1	131	2.9	118	2.6	22	0.5	143	3.1	0.8
	Liver	16	0.4	2	0.04			12	0.3	1	0.02			14	0.3	0	0			
WP4																				
Romania	Kidney	75	3.6	159	7.3	152	7.7	53	2.8	154	8.9	148	7.2	54	2.7	212	12.0	200	10	2.3
	Liver	8	0.4	53	2.5			20	1.1	75	4.0			14	0.7	108	5.4			
Turkey	Kidney	2433	32.5	521	6.9	3987	53.3	2383	31.5	524	6.9	4013	53	2359	30.7	585	7.6	4294	56	2.7
	Liver	623	8.3	281	3.7			736	9.7	265	3.5			959	12.5	289	3.8			

Abbreviations: Abs, absolute; pmp, per million people; WP, work package.

Improving the knowledge and communication skills of health care professionals and the general public is essential for optimizing and increasing organ donation. A total of 62.5% of analyzed BSA countries had started training programs to harmonize practices for staff involved in the transplantation and procurement of organs. In terms of public awareness, 50% of the countries analyzed had undertaken efforts such as providing communication guidelines to inform the public, periodic meetings with journalists, and monitoring of newspaper articles. Results show that only 25% of the countries analyzed had undertaken continuous education campaigns in schools and universities [18].

Organ Donation Activity

The rate of total organ donation increase per million people (pmp) (Δ total organ donation [pmp] 2013–2011 = total donation 2013 – total donation 2011) was as follows: Azerbaijan, +7.3 pmp; Armenia, –0.7 pmp; Georgia, +3.3 pmp; Bulgaria, +0.9 pmp; Moldova, +2.5 pmp; Ukraine, +0.8 pmp; Romania, +2.3 pmp; and Turkey, +2.7 pmp. Table 2 provides detailed information about organ donation rates growth in BSA participant countries, including living and deceased donation rates.

Transplantation Activities

Table 3 shows the number of transplantation centers in BSA participant countries.

DISCUSSION

BSA countries are geographically related, but results indicate that they have different needs and levels of development of donation and transplantation activities. Hence, no general strategy was implemented as part of this project.

Collaborations between participant member states were proposed based on experience and existing relationships.

National Implication and International Cooperation

The results indicate that nomination of a national focal point (government contact) is essential. Direct communication with the Ministry of Health is necessary to coordinate and ensure communication, meet project deadlines, and develop and implement concrete actions. However, it was also recognized that political instability and, in particular, continuous changes within the Ministry of Health of some of these countries hampered the completion of multiple interventions in the area. During the project, a lack of involvement by some national authorities was detected. Extra effort should be made to ensure better communication and participation of national authorities to increase the positive impact of the project. Meetings with NFPs were essential for action plan progress, and commitment from the Ministry of Health was also critical. The results show that steps might be taken to increase the effectiveness of these meetings. BSA participant countries should be encouraged to provide valuable information without the need for a face-to-face meeting (teleconferences, regular telephone calls, emails). These actions could positively impact the relationship between BSA MSs and lead countries.

BSA countries should also explore possibilities to access structural funds within the health care system to organize transplant programs and activities.

BSA countries in WP3 and WP4 have an NTO responsible for the national coordination of donation and transplantation activities. It is essential to establish official organizations in Azerbaijan, Armenia, and Georgia for managing, overseeing, and supporting donation and transplantation activities at the national level.

Learning from each other is potentially a solid strategy to improve organ donation, especially considering the rich

Table 3. Number of Transplant Centers in the Black Sea Area Participant Countries in 2014

	WP2			WP3		WP4		
	Armenia	Azerbaijan	Georgia	Bulgaria	Moldova	Ukraine	Romania	Turkey
Kidney center								
Living donation centers	1	1	3	3	1	2	5	62
Deceased donation centers	–	–	–	1	2	7	5	62
Liver center								
Living donation centers	–	–	–	3	1	1	1	38
Deceased donation centers	–	–	–	3	1	1	1	38
Heart center								
Living donation centers	–	–	–	–	–	–	–	–
Deceased donation centers	–	–	–	2	1	1	2	12
Lung center								
Living donation centers	–	–	–	–	–	–	–	–
Deceased donation centers	–	–	–	–	–	–	–	6
Pancreas center								
Living donation centers	–	–	–	–	–	–	–	–
Deceased donation centers	–	–	–	–	–	–	–	4

Abbreviation: WP, work package.

diversity within the BSA area. However, the potential to learn from other countries was underused, although all BSA countries participated in ≥ 1 European project between 2010 to 2014. It is essential to coordinate future efforts and initiatives to promote donation and transplantation of organs to avoid overlapping or duplicating actions.

Deceased Donation Activity

Deceased donation programs are included in the national healthcare agenda of most BSA countries. The tasks of donor coordinators differ between countries, ranging from a predominantly administrative role to the identification of potential donors. Almost all donor coordinators receive training, but this training is rarely evaluated; this factor can be improved. Furthermore, development of a common accreditation scheme could be valuable. WP2 countries could learn from the experience of other countries and accredit transplant procurement management system. The positive application of transplant procurement management systems in the process of living and deceased donation should be evaluated regularly.

Living Donation Activity

All BSA countries analyzed had ongoing living donation programs, and most have established separate bodies to evaluate living donors. This number has increased slightly since 2010, but not all countries have such bodies. Most BSA countries need to establish registries to evaluate and guarantee the health and safety of living donors. Many countries have taken up living donation, so this is becoming an important next step. Those countries that have not yet done so should establish registers and begin monitoring the health and safety of living donors over longer periods of time.

Educational Programs

Most countries have adopted various initiatives to enhance educational programs so that the quality of the organ donation process is improved. Unfortunately, according to our evaluation, they did not achieve the expected results. Training initiatives have been focused on stimulating the quality of follow-up care and the transplantation process, but quality improvement should cover the full cycle of procurement, transplantation, and evaluation. Almost all coordinators and health care professionals received training, but this training was often not evaluated. This can be improved.

Schemes to increase awareness among the general population about donation have seemingly been undertaken in most of the countries, but not always in a systematic way. One possible strategy may be to start developing national communication plans on organ donation.

In conclusion, the BSA project has contributed to the development of transplantation activities in participant countries by providing expertise and guidance. Thanks to the project, it was possible to analyse, assess, and compare

the different legal and organizational systems in various BSA countries. The BSA project also evaluated each participant country and provided tailored recommendations, guidelines, and educational tools to enhance and consolidate their organ donation and transplantation systems.

BSA countries have different legal and organizational systems. Some have a tightly monitored and well-developed system of organ donation but a wide gap between organ supply and demand. In other countries, the system of organ donation is in its infancy. The number of participants involved in the donation and transplantation of organs is another problem faced by these countries. In some countries living donation is vital, whereas in others the priority is deceased donation.

The BSA project was carried out with the input and contribution of CoE representatives, ministries of health, country leaders, and health care professionals involved in the process of donation and transplantation of organs in BSA countries. The challenge was to find suitable solutions considering the diversity present in the region (and even to make good use of it) through projects and supportive actions that take these differences into account. In this way, the BSA project might reduce the gap between the demand and availability of organ donors to make transplant systems more efficient and transparent, as well as to improve quality and safety.

As a consequence of the project outcomes, BSA countries should invest in the implementation of these recommendations at 3 levels, administrative, national organization and hospitals level, to achieve a self-sufficient system for the donation and transplantation of organs. The data analyzed provided show that BSA member states need to have real political interest and engagement to develop these activities.

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REFERENCES

- [1] Statute of the Council of Europe. <http://conventions.coe.int/treaty/en/treaties/html/001.htm>. [Accessed 21 October 2017].
- [2] European Committee on Organ Transplantation (CD-P-TO). www.edqm.eu/en/organ-transplantation-work-programme-72.html. [Accessed 21 October 2017].
- [3] Joint Study on Trafficking in Organs, Tissues and Cells and Trafficking in Human Beings for the Purpose of the Removal of Organs. <https://rm.coe.int/16805ad1bb>. [Accessed 21 October 2017].
- [4] Council of Europe Convention on Action against Trafficking in Human Beings. <https://rm.coe.int/168008371d>. [Accessed 21 October 2017].

- [5] Declaration of Istanbul. <http://www.declarationofistanbul.org/>. [Accessed 21 October 2017].
- [6] European Parliament and Council of the European Union. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. 2010. Official Journal of the European Union 2010;53:14–29. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0053>. [Accessed 21 October 2017].
- [7] Groth S, Noël L, Matesanz R, Domínguez-Gil B, Chapman J, Delmonico F, et al. Third WHO Global Consultation on Organ Donation and Transplantation: striving to achieve self-sufficiency, March 23–25, 2010, Madrid, Spain. *Transplantation* 2011;91(Suppl. 11):S27–8.
- [8] Delmonico FL, Domínguez-Gil B, Matesanz R, Noel L. A call for government accountability to achieve national self-sufficiency in organ donation and transplantation. *Lancet* 2011;378:1414–8.
- [9] Council of Europe Committee of Ministers. Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances. [http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res\(78\)29E.pdf](http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/Res(78)29E.pdf). [Accessed 21 October 2017].
- [10] Manyalich M, Guasch X, Paez G, Valero R, Istrate M. ETPOD (European Training Program on Organ Donation): a successful training program to improve organ donation. *Transpl Int* 2013;26:373–84.
- [11] Manyalich M, Valero R, Paez G, Ballesté C, Sandiumenge A. Transplant procurement management: TPM. Organisational model for the generation of donors. In: *Transplant Coordination Manual*. Barcelona: TPM-DTI Foundation; p. 9-30.
- [12] López-Fraga M, Domínguez-Gil B, Fehily D, Chatzixiros E, Fischer-Fröhlich C, Arredondo E, et al. Concerted efforts to promote donation and transplantation in Europe: the leading role of the Council of Europe and the CD-P-TO. *Organs Tissues Cells* 2014;17:39–48.
- [13] Recommendation Rec(2006)15 of the Committee of Ministers of the Council of Europe to member states on the background, functions and responsibilities of a National Transplant Organisation (NTO). <https://wcd.coe.int/ViewDoc.jsp?id=1062653&Site=CM>. [Accessed 21 October 2017].
- [14] Matesanz R, Domínguez-Gil B, Coll E, de la Rosa G, Marazuela R. Spanish experience as a leading country: what kind of measures were taken? *Transpl Int* 2011;24:333–43.
- [15] Domínguez-Gil B, Delmonico FL, Shaheen FA, Matesanz R, O'Connor K, Minina M, et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transpl Int* 2011;24:373–8.
- [16] 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. <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>. [Accessed 21 October 2017].
- [17] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin. <http://conventions.coe.int/Treaty/en/Treaties/Html/186.htm>. [Accessed 21 October 2017].
- [18] European Day for Organ Donation & Transplantation. <http://www.edqm.eu/en/European-day-for-organ-donation-1223.html>. [Accessed 21 October 2017].