CONCERTED EFFORTS TO PROMOTE DONATION AND TRANSPLANTATION IN EUROPE: THE LEADING ROLE OF THE COUNCIL OF EUROPE AND THE CD-P-TO

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Summary - Organ donation and transplantation are complex and rapidly-evolving fields, capable of saving and improving the lives of thousands of patients worldwide, but also having their own inherent challenges. These challenges include ensuring effective organisation, co-ordination and control of all crucial technical activities and services (removal, transportation, processing, preservation, quality control and, where necessary, storage) and safeguarding against exploitation and misuse. The Council of Europe is a pioneering institution for the protection of human rights, democracy and the rule of law. Since 1987, it has also been an active and key player in the field of transplantation in Europe. Through a number of initiatives, programmes and legal instruments, the Council of Europe has actively contributed to the development and implementation of quality and safety standards in the field of donation and transplantation, facilitating the exchange of knowledge between countries and institutions, securing fundamental rights and ensuring respect for the human body. Here, we summarise the work of the Council of Europe in this area, and highlight how international collaborative efforts are the most effective way to achieve the common goal of saving and improving the lives of patients.

Introduction

We are now entering into a new age of medical progress. Medical procedures that were unimaginable a generation ago are a reality today. Many of these developments, such as advances in transplantation therapy and regenerative medicine, have unquestionable benefits, but the utilisation of human organs, tissues and cells (OTC) also poses questions of safety, quality and efficacy and presents new ethical dilemmas. In order to overcome such barriers and to facilitate access to safe and ethical transplantation therapy for all European citizens, the Council of Europe started working in this area back in 1987.

The Council of Europe, based in Strasbourg (France), is an international organisation that promotes co-operation

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among all European countries in the areas of human rights, democracy, rule of law, culture and public health. Founded in 1949 by the *Treaty of London* (1), the Council of Europe includes 47 member states (MS) and encompasses 820 million citizens (Figure 1). The Council of Europe is an entirely separate body from the European Union (EU), the latter having 28 MS that have conferred some national legislative and executive powers from the national to the EU level with the aim of achieving a higher level of integration. In contrast, Council of Europe MS maintain their sovereignty, but co-operate on the basis of common values and political decisions and commit themselves through Treaties. No country has ever joined the EU without first belonging to the Council of Europe.

Following the *Third Conference of European Health Ministers on the Ethical, Organisational and Legislative Aspects of Organ Transplantation* (2), held in Paris (France) in 1987, the Council of Europe *Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation* (SP-CTO) was created. This Committee consisted of experts on the different aspects of the transplantation field - immunologists, surgeons, physicians, co-ordinators and representatives from organ-sharing and organ procurement organisations. In 2007, the Secretariat responsible for activities related to OTC was transferred to the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe, and the newly-appointed *European Committee on Organ Transplantation* (CD-P-TO) took over as the Steering Committee (3) (Table 1). This move to the EDQM facilitated closer collaboration and synergies with the EU and aimed, amongst other objectives, to avoid duplication of efforts. This was a real danger after 2004 when, following adoption of its new competencies, the EU started issuing Directives and sets of technical requirements in the field (4).

Today, the CD-P-TO is composed of internationally-recognised experts from Council of Europe MS, observer countries, the European Commission, the World Health Organization (WHO), representatives from the Committee on Bioethics of the Council of Europe (DH-BIO) and several non-governmental organisations. It actively promotes the non-commercialisation of organ donation, the fight against organ trafficking, the development of ethical, quality and safety standards in the field of OTC, and the transfer of knowledge and expertise between MS and organisations.

This article provides an updated overview of the main initiatives carried out by the Council of Europe and the CD-P-TO, highlighting the value of integrated European responses in combatting organ shortage and unethical practices, and resolving common challenges in the field of OTC.

Chairmen of the European Committee (Partial Agreement) on Organ Transplantation (CD-P-TO) and predecessor Committees	
1988 - 1995	HORS Jacques (FRANCE)
1995 - 2000	MATESANZ Rafael (SPAIN)
2000 - 2003	DOYLE Peter (UK)
2003 - 2005	MATESANZ Rafael (SPAIN)
2005 - 2010	LOTY Bernard (FRANCE)
2010 - 2012	PFEFFER Per (NORWAY)
2012 -	NANNI COSTA Alessandro (ITALY)

TABLE 1

FIGURE 1 - Geographic region of the Council of Europe. It includes 47 member states, 28 of which are members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law.

Legal guidance and international monitoring

Over the years, a set of Resolutions and Recommendations in the field of OTC have been produced and subsequently adopted by the Committee of Ministers of the Council of Europe (Table 2). The first of these documents, *Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances* (5), was a milestone in promoting uniformity in the legal approach to the numerous aspects of this practice, later reflected in the *Convention on Human Rights and Biomedicine* (6) and its *Additional Protocol* concerning transplantation (7).

In an attempt to address organ shortage, a number of organisational aspects critical to the process of donation

after death have been the subject of several recommendations, including the responsibilities of national transplant organisations, the role and training of donor transplant co-ordinators, the development of quality assurance programmes to continuously assess performance in the process of deceased donation, the management of waiting lists and the role of organ donor registries, amongst others (8). Additionally, a compendium of specific strategies that must be developed by any MS in order to optimise every step of the process of donation after death was comprehensively developed in the reference document *Organ Shortage: Current Status and Strategies for the Improvement of Organ Donation* (9).

Advances in the field of transplantation have been tackled in a highly innovative manner by the Council of Europe through the elaboration of legal instruments that address emerging challenges, e.g. xenotransplantation and cord blood banking. Regarding the latter, a firm position has been taken in recommending MS to allow the establishment of cord blood banks only on the basis of altruistic and voluntary cord blood donation (10). More generally, the promotion of cord blood donation for autologous use and the establishment of cord blood banks for autologous use should not be supported by MS or their health services but, where they already exist, transparent information should be given to the public on existing medical indications.

The position of the Council of Europe on live organ transplantation has evolved over the years, as evidenced through different legal instruments. The initially conservative approach towards living organ transplantation reflected in the *Convention on Human Rights and Biomedicine* has evolved to the recent adoption of *Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes* (11). Building on the concept that living dona-

Recommendations and Resolutions produced and adopted by the Council of Europe´s Committee of Ministers in the field of donation and transplantation of organs, tissues and cells
Resolution (78) 29 on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances.
Recommendation No. R (94) 1 of the Committee of Ministers to member states on human tissue banks.
Recommendation No. R (97) 15 of the Committee of Ministers to member states on xenotransplantation.
Recommendation No. R (97) 16 of the Committee of Ministers to member states on liver transplantation from living related donors.
Recommendation No. R (98) 2 of the Committee of Ministers to member states on provision of haematopoietic progenitor cells.
Recommendation Rec(2001)5 of the Committee of Ministers to member states on the management of organ transplant waiting lists and waiting times.
Recommendation Rec(2003)10 of the Committee of Ministers to member states on Xenotransplantation and its Explanatory Memorandum.
Recommendation Rec(2003)12 of the Committee of Ministers to member states on organ donor registers.
Recommendation Rec(2004)7 of the Committee of Ministers to member states on organ trafficking.
Recommendation Rec(2004)8 of the Committee of Ministers to member states on autologous cord blood banks and its Explanatory Memorandum.
Recommendation Rec(2004)19 of the Committee of Ministers to member states on criteria for the authorisation of organ transplantation facilities.
Recommendation Rec(2005)11 of the Committee of Ministers to member states on the role and training of professionals responsible for organ donation (transplant "donor co-ordinators").
Recommendation Rec(2006)15 of the Committee of Ministers to member states on the background, functions and responsibilities of a National Transplant Organisation (NTO).
Recommendation Rec(2006)16 of the Committee of Ministers to member states on quality improvement programmes for organ donation.
Resolution CM/Res(2008)4 on adult-to-adult living donor liver Transplantation.
Resolution CM/Res(2008)6 on transplantation of kidneys from living donors who are not genetically related to the recipient.
Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system.
Resolution CM/Res(2013)56 on the development and optimisation of live kidney donation programmes and its Explanatory Memorandum.

TABLE 2

tion is a necessary adjuvant in the pursuit of self-sufficiency in transplantation, this Resolution invokes the need to pre-emptively present the option of live kidney transplantation, to overcome legal and technical obstacles, and to ensure comprehensive protection of living organ donors. The specificities of liver living donation and the basis for unrelated living donation programmes have also been the subject of specific recommendations to MS embarking on such strategies.

Although not legally binding, all these documents have profoundly impacted national legislations, ethical frameworks, strategic plans on organisational aspects of donation and transplantation, and professional practices. Today, with the EU setting down precise regulatory frameworks in the form of Directives, these recommendations support countries both inside and outside the EU to address the many challenges posed by transplantation practices in a uniform manner.

Monitoring of practices in the MS has become an evident need for the sake of transparency and international benchmarking. Keeping this goal in mind, the EDQM/Council of Europe has published since 1996 the *Newsletter Transplant* (12), which is co-ordinated by the Spanish National Transplant Organization. This publication summarises comprehensive data provided by national focal points designated by governments on donation and transplantation activities, management of waiting lists, organ donation refusals and authorised centres for transplantation activities. As of today, the *Newsletter Transplant* provides information from almost 70 countries worldwide, including Council of Europe MS, observer countries and observer networks (e.g. Iberoamerican Donation and Network Council on Organ Donation and Transplantation, Mediterranean Network). The *Newsletter Transplant* database is connected with other international data collection projects, e.g. the WHO Global Observatory on Organ Donation and Transplantation and the Eurocet database, to avoid duplication of efforts. The *Newsletter Transplant* has evolved into a unique official source of information that continues to inspire policies and strategic plans globally.

Fight against organ trafficking

Despite worldwide initiatives to enlarge the donor pool, organ shortage remains the main obstacle in transplant medicine and no country is yet able to meet the transplantation needs of its patients. Under these circumstances, desperate patients may seek organs outside legal transplantation networks, and unscrupulous medical professionals and an array of intermediaries take advantage of a highly profitable, unethical and vulnerable market. This occurs at the expense of exploited human beings, whose organs are removed and whose health generally worsens in the medium-term due to the absence of appropriate screening, appropriate follow-up, hard physical work and unhealthy lifestyles. Similarly, in many cases, patients seeking trafficked organs return home with very poor quality organs, infections and malignancies, which may result in them losing their newly-acquired organ and even their life (13-18). Trafficking in human beings for the purpose of organ removal (HTOR) and trafficking in human organs (THO) are real and growing problems all over the world. According to the WHO, 5-10% of all transplants performed worldwide are conducted illegally (19), and it has been estimated that the illicit organ trade generates illegal profits of between $600 million and $1.2 billion per year (20). Trade in human organs has been ranked number 10 out of the top 12 illegal profit-making activities (20).

The issue of organ trafficking is not new. In the 1980s, experts began to notice what was to become known as "transplant tourism". The most common form of this practice is when patients travel abroad to be transplanted with organs in exchange for payment. This phenomenon is booming, partly because the less restrictive regulations of certain countries allow such "transactions" or do not expressly prohibit them, or because law enforcement mechanisms are lacking. But also because "client countries" have not adopted measures to dissuade patients from travelling abroad to be transplanted under circumstances that would be deemed illegal in their countries of origin, e.g. by establishing extra-territorial jurisdiction over crimes committed abroad.

The most frequently encountered form of trafficking related to organ transplantation involves living unrelated donors. However, deceased donors can also be a source of trafficked organs. In some South American and Asian countries, kidneys, livers and hearts from deceased donors have been sold to patients requiring transplants. Furthermore, in China, organs from executed prisoners are used for the majority of the transplants performed in the country (21).

The principle that use of the human body and its parts must not give rise to financial gain is a fundamental tenet of the Council of Europe. This principle, already present in Resolution (78) 29 of the Committee of Ministers (5), was enacted by Article 21 of the *Convention on Human Rights and Biomedicine* (6) and then reiterated in the *Additional Protocol on Transplantation of Organs and Tissues of Human Origin* (7), opened for signature in January 2002.

In *Recommendation 1611 (2003) on trafficking in organs in Europe* (22), the Council of Europe's Parliamentary Assembly already suggested that a European strategy be developed to combat organ trafficking and, particularly, that a Council of Europe Convention against these practices should be drafted.

Subsequently, the Council of Europe *Convention on Action against Trafficking in Human Beings* (23), which explicitly mentions the exploitation of individuals for the removal of organs as a condemnable practice, was opened for signature in May 2005 and entered into force in February 2008. Taking the United Nations *Convention against Transnational Organized Crime and its Protocol to Prevent, Suppress and Punish Trafficking in Persons, especially Women and Children* (24) as a starting point, the Council of Europe Convention sought to strengthen the protection afforded by existing legal tools.

In 2009, the Council of Europe and the United Nations published *a Joint Study on Trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs* (25). This study clearly identified HTOR and THO as different crimes. Both crimes have the same purpose (i.e. obtaining an organ) and largely the same root cause (i.e. organ shortage), but their scope is different; the former involves exploitation of the person whose organ is solicited and the latter does not. In fact, HTOR may be considered a particularly heinous form of THO, characterised by the use of coercive means to obtain an organ. Although THO may arise from cases of HTOR, THO may also occur with no link to cases of HTOR; for example, when the trafficked organ comes from a deceased person or when the donor has voluntarily and freely provided informed consent to sell his/her organ. The *Joint Study* also identified the lack of an internationally accepted definition for THO and some clear loopholes in the existing international legislation covering crimes related to THO not arising from HTOR.

In this context, the Council of Europe decided to draft a new Convention against THO, which will also be open for signature and ratification to non-Council of Europe MS. This Convention will offer a universal legal framework on THO, providing clarity on how the practice must be prosecuted, and including provisions to combat and prevent the practice and to protect and assist its victims. Monitoring mechanisms will also be established under this new Convention to ensure the effective implementation of its provisions and to facilitate international co-operation. This Convention is expected to be adopted by the Committee of Ministers in the coming months.

Aware that targeted data collection is critical for curtailing unethical practices related to transplantation, the CD-P-TO recently drafted *Resolution CM/Res(2013)55 on establishing procedures for the collection and dissemination of data on transplantation activities outside a domestic transplantation system* (26), which was adopted by the Council of Europe's Committee of Ministers in December 2013. Through this Resolution, Council of Europe MS are recommended to designate a contact person with the responsibility of regularly collecting data on patients travelling abroad to receive illicit transplants and to develop and implement appropriate tools for such data collection.

The CD-P-TO has also established a number of collaborations with international bodies actively working to tackle HTOR and THO, particularly with the Declaration of Istanbul Custodian Group, whose mission is to promote, implement and uphold the *Declaration of Istanbul* (27), a statement driven by The Transplantation Society and the International Society of Nephrology, with a view to combatting organ trafficking, transplant tourism and transplant commercialism and encouraging the adoption of effective and ethical transplantation standards around the world.

Overall, within the comprehensive legal framework and body of recommendations built up under the auspices of the Council of Europe, the CD-P-TO has become a critical stakeholder in the fight against illegal organ trade.

International collaborative programmes

The WHO has called for self-sufficiency in transplantation, a new paradigm that involves governments taking national responsibility for fulfilling the organ donation and transplantation needs of patients by accessing resources from within their own populations (28). However, organ availability and hence patient access to organ transplantation vary among different countries (12). Several possible factors contribute to this variability, such as differences in legislation, management and organisation of deceased organ recovery programmes, as well as the extent of tailored training for active professionals in this field. Over the last few years, the Council of Europe and the WHO began to implement projects supporting the development of a common and constructive attitude towards transplantation issues in various countries. Efforts were mainly directed towards the development of effective legislative frameworks and the establishment of national transplant authorities and transplant programmes.

In 2004, the Council of Europe and the European Commission agreed upon a Joint Programme for the Republic of Moldova, which focused on transplantation services and combatting organ trafficking. As a result of these activities, a new law on transplantation was developed and adopted by the Moldovan Parliament in 2008 and a Transplant Agency was established that is now responsible for all organisational aspects in this field. Following the Moldovan experience, it became evident that experiences from countries with well-developed and established transplantation programmes should be shared and that local initiatives could provide models for increasing transplantation activity and for the implementation of safety and quality programmes throughout Europe.

A dedicated programme was then proposed to promote organ donation and transplantation throughout the entire Black Sea area (BSA). The BSA Project, a three-year initiative launched in July 2011, is built on the philosophy that Council of Europe MS with established and successful transplant systems transfer their knowledge and experience to the BSA countries. The Council of Europe provides political and logistical support to the project.

Nine countries (Armenia, Azerbaijan, Bulgaria, Georgia, Moldova, Romania, Russian Federation, Turkey and Ukraine) were invited to collaborate, with the support of experts from the CD-P-TO. Although these countries share the same regional area, they are very different in terms of their current approaches to transplantation and the extent of resources assigned to the field. As a result, the interventions prescribed under the programme had to be multi-level and country-specific.

The work under the project was targeted at two levels: first, working with governments and Ministries of Health to engage political involvement through site visits and direct meetings and, second, working directly at a technical level with national experts. After an initial phase of data collection through questionnaires and site visits, the participating BSA countries were assigned different priorities based on the current level of development of their transplantation activities and needs, as follows:

- *Development and implementation of effective legislative and financial frameworks:* This priority aims at developing and implementing effective legislative and financial frameworks for transplantation activities. This priority is especially important for Armenia, Azerbaijan and Georgia, that have basic legislation on organ transplantation, minimal organ transplantation activity from living donations, and no deceased donation programmes. The actions aim at assessing the existing transplant legislation and financial provisions for their healthcare programmes and transplantation activities, identifying institutional and structural obstacles to the development of transplantation, and promoting the political will necessary to develop such programmes.
- *Establishment of national transplant authorities:* This priority aims at establishing adequate organisation and co-ordination of transplantation activities at a national level. This priority is especially important for Bulgaria, Moldova and Ukraine, which already have established National Transplant Organisations but minimal or no deceased donation. The actions focus on the evaluation of these existing organisational systems and their functionality in order to identify areas for intervention and improvement.
- *Improvement of clinical practices:* This priority targets the analysis of clinical practices for the donation-transplantation process inside hospitals. It is tailored to Romania, the Russian Federation and Turkey, who have established National Transplant Organisations and have fully functional living and deceased donation programmes, but donation rates remain low. The actions focus on the evaluation of procedures and practices at local/hospital level in order to provide solutions for improvement.

Based on the defined priorities for each BSA country, specific tasks and goals have been established for each one and appropriate training is provided to accomplish them. There is continuous follow-up of progress.

International collaboration under such programmes can provide solutions for achieving self-sufficiency. It is clear that a universal recipe for success does not exist and, therefore, programmes need to be adapted to the individual socio-economic circumstances of each Council of Europe MS. Effective legislative and regulatory frameworks should be in place before focusing on clinical practices and, in all cases, effective transplantation programmes require committed, continuous and sustainable political and financial investment and support.

Technical guidance to improve the quality and safety of organs, tissues and cells

In 1999, the Council of Europe set up a working group to prepare a guide on the standards required and the quality assurance that should be achieved in services for the donation, procurement and transplantation of human OTC in MS. The first edition of this *Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells* was published in 2002, with a plan for regular updates. In the meantime, the EU adopted *Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells* (29), which was followed by a number of Directives regulating the field of OTC donation and transplantation. These legally-binding documents arose from the competence laid down in Article 168 of the *Treaty on the Functioning of the European Union* (30), by which the EU could adopt measures setting high standards of quality and safety for substances of human origin. The Council of Europe and the European Commission then began to co-operate further to ensure that the standards set out under these Directives were compatible with and complemented by the Council of Europe guide. This collaboration ensures that the same quality and safety standards are being applied throughout Europe.

During the revision of the 4th edition of the guide in 2011, it became clear that the fields of organ transplantation and tissue and cell transplantation required a different approach in terms of safety and quality provisions.

In particular, the often complex processes involved in the preparation, preservation and storage of tissues and cells meant that considerable additional detail was required to provide useful guidance for that field. It was decided to separate the existing document into two new guides; one that dealt with organs, i.e. *Guide to the quality and safety of organs for transplantation* (currently in its 5th edition), and the other with tissue- and cell-specific requirements, i.e. the new *Guide to the quality and safety of tissues and cells for human application* (31).

Both guides are the result of the efforts of experts from all over the world who have contributed different aspects and have done a tremendous job in reviewing the literature and extracting knowledge from numerous international guidelines, collaborative projects and diverse publications and websites, with the aim of ensuring access to all this information. Several professional associations actively participate in the elaboration of these guides, most notably the European Donation and Transplant Coordination Organization (EDTCO), the American Association of Tissue Banks (AATB) and the European Association of Tissue Banks (EATB). In addition, both guides are submitted to public consultation, which allows professionals and regulators from Council of Europe MS to review the entire content, provide comments and suggest changes.

The *Guide to the quality and safety of organs for transplantation* collates updated information to provide professionals with a useful overview of the most recent advances in the field: from the identification, assessment and maintenance of potential donors to organ procurement and preservation strategies, risk assessments for poisoning and the transmission of infectious, neoplastic and other diseases, reporting of adverse events and reactions and quality management in organ donation. The guide aims at increasing safety for patients on waiting lists and for recipients of organs, while minimising organ wastage and under-utilisation of potential donors, by providing recommendations based on available evidence and expert opinion to physicians engaged in donor detection, transplant co-ordinators managing the donation process, and transplant physicians and surgeons responsible for organ assessment, allocation, transplantation and subsequent follow-up of transplant recipients. The recommendations in the guide are fully aligned with Directives 2010/53/EU (32) and 2012/25/EU (33), comprising a set of minimal essential and mandatory requirements but, where necessary, providing further and detailed guidance.

The *Guide to the quality and safety of tissues and cells for human application* focuses on the complex processes involved in the preparation, preservation and storage of tissues and cells. This guide draws on a number of relevant initiatives, notably the EU-funded EuroGTPs (34), EUSTITE (35) and SOHO V&S (36) projects, the standards of the American Association of Tissue Banks and the FACT/JACIE standards for haematopoietic stem cells. The guide is divided into two sections. Section A contains general requirements applicable to all establishments involved in the donation, procurement, testing, processing, preservation, storage and distribution of any type of tissues or cells. Section B contains specific guidelines and requirements for the different tissue and/or cell types. The guidelines apply only to tissues and cells intended for clinical use (including transplantation or assisted reproduction), but not those used for in vitro research.

Like the guide for organs, the guide for tissues and cells aims to support all those working in donation, processing and clinical use of tissues and cells in Council of Europe MS. It is fully aligned with Directives 2004/23/EC (29), 2006/17/EC (37), 2006/86/EC (38) and 2012/39/EU (39), adding further guidance and recommendations where appropriate, and even proposing the application of more restrictive technical practices in specific circumstances. For example, while the EU Directives require tissues or cells exposed to the environment without subsequent sterilisation to be handled as a minimum in a grade A environment with a grade D background (according to GMP) (40), the guide proposes that a risk assessment should be undertaken for each type of substance and process. This assessment could result in a higher standard (A in B or A in C), though not a lower one, being prescribed than that of the EU Directives, depending on the preparation process, the type of tissue or cell and the clinical application.

Both guides are essential tools to help physicians, transplant co-ordinators and tissue bankers in the EU apply the safety and quality standards outlined in the relevant EU Directives by providing practical advice on how to implement EU requirements in their daily practice. For example, while the EU Directives require risk assessments to be conducted in various situations, the guides provide practical explanations and algorithms on how to evaluate the risk of transmission of malignancies, infectious and genetic diseases, etc.

The guides also provide detailed technical guidance that cannot be included in legally binding instruments such as Directives that are not easily updatable. For example, the *Guide to the quality and safety of organs for transplantation* provides clinical guidance on the patho-physiological management of potential donors after brain death. Similarly, the *Guide to the quality and safety of tissues and cells for human application* provides guidance on quality control tests that should be part of the release criteria for specific tissues and cells (e.g. endothelial cell counting for corneas, functional capacity testing for heart valves, osteo-inductivity demonstration for demineralised bone preparations), guidance on storage temperatures and times for specific tissues

and cells, and methods and examples for validation and qualification of equipment.

In addition to providing practical support to health professionals working within the EU and beyond, these guides serve as invaluable tools for regulators and practitioners throughout Europe, especially in those countries that do not have specific legislation regulating donation and transplantation activities.

Finally, many developments in transplantation and regenerative medicine have unquestionable benefits, but using human OTC also raises important ethical dilemmas. The introductory chapters of both guides provide an ethical framework for the donation and transplantation of OTC. In later chapters, detailed principles and guidelines form the basis for recommendations on consent, allocation on the basis of fairness and other criteria, and clinical need.

The 6th edition of *the Guide to the quality and safety of organs for transplantation* will be published in 2016 and will contain new chapters on determination of death by neurologic criteria and specific chapters dealing with the specificities of donation after circulatory death and living donation, both of which representing activities that are increasing exponentially in Europe.

The 2nd edition of the *Guide to the quality and safety of tissues and cells for human application* will be published in 2015. In addition to updating the existing contents, it will include several new chapters on assisted reproduction, fertility preservation, general principles of microbiological testing, and novel and more extensively manipulated tissues and cells.

European Day for Organ Donation and Transplantation

With the aim of increasing public outreach on organ donation and transplantation, the first celebration of the European Day for Organ Donation and Transplantation (EODD) (41) took place in Geneva in 1996 with the support of the Council of Europe. In 1998, the Council of Europe took over the organisation of the EODD and established the practice that each year a different MS would host the main celebration on the second Saturday of October. Over the years, the concept of accompanying satellite celebrations, happening simultaneously in different European cities, became increasingly popular.

The main objectives of the EODD are to raise public awareness and establish trust among the general public towards responsible, ethical, non-commercial and professional organ donation and transplantation, to engage policy-makers and the medical community, and to encourage public debate and provide information so that each person can decide on donation and make his/her wishes known to their family. EODD is also an opportunity to honour all organ donors and their families and to thank transplantation professionals throughout Europe whose hard work helps to save lives and improve the quality of life of many people.

This year, Rome (Italy) will host the 16th edition of EODD on 11 October 2014.

Conclusions

The Council of Europe, through the CD-P-TO and its working groups, has been a pioneer in establishing quality, safety and ethical guidelines for OTC donation and transplantation in Europe and continues to deliver an ambitious work programme in support of its 47 MS. The Council of Europe has implemented an effective approach of adopting the relevant EU Directives as minimum requirements for safety and quality, while adding value by defining ethical principles, providing detailed technical guidance and establishing collaboration programmes to support the development of transplantation programmes in areas where they are in their early stages.

This work is valuable to policy makers and inspectors in EU MS because it defines the best practices for the implementation of the relevant EU Directives. This guidance supports inspection activities, and reveals where future modifications and enhancements in the legislation may be made.

Perhaps even more importantly, the work of the Council of Europe provides a comprehensive framework for MS outside the EU. This framework covers all aspects of the implementation of transplantation programmes, from establishing ethical legislation to the implementation of safety and quality standards consistent with those of neighbouring EU MS. From a practical point of view, projects such as the BSA initiative support the recommendations and guidance by providing assistance with implementation at the policy-making, regulatory and professional levels.

The work of the Council of Europe in this field is supported by the EDQM's technical officers and a very large number of dedicated individuals from health authorities, professional societies and experts from organisations providing OTC donation and transplantation services across Europe and beyond. The results of their work strengthen the existing mechanisms for co-operation in the crucial fight against organ trafficking and in achieving the shared objective of making donation and transplantation available, ethical, safe and effective for all.

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