

# Organ donation and transplantation

## Facts, figures and European Union action

### SUMMARY

The issue of organ donation and transplantation gained renewed political momentum as one of the initial health priorities of the current Croatian Presidency of the Council of the EU.

There are two types of organ donation: deceased donation and living donation. Organ transplantation has become an established worldwide practice, and is seen as one of the greatest medical advances of the 20th century. Demand for organ transplantation is increasing, but a shortage of donors has resulted in high numbers of patients on waiting lists.

Medical, legal, religious, cultural, and ethical considerations apply to organ donation and transplantation. In the EU, transplants must be carried out in a manner that shows respect for fundamental rights and for the human body, in conformity with the Council of Europe's binding laws, and compliant with relevant EU rules. World Health Organization principles also apply.

Organ donation rates across the EU vary widely. Member States have different systems in place to seek people's consent to donate their organs after death. In the 'opt-in' system, consent has to be given explicitly, while in the 'opt-out' system, silence is tantamount to consent. Some countries have donor and/or non-donor registries.

Responsibility for framing health policies and organising and delivering care lies primarily with the EU Member States. The EU has nevertheless addressed organ donation and transplantation through legislation, an action plan and co-funded projects, and the European Parliament has adopted own-initiative resolutions on aspects of organ donation and transplantation.

Stakeholders have submitted a joint statement on a shared vision for improving organ donation and transplantation in the EU. An evaluation of the EU's action plan identified the need for a new, improved approach. Innovative products and procedures, such as artificially grown organs and 3D bio-printing, might lend themselves as future possibilities to reduce our reliance on organ donors.



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## Glossary

**Donor after brain death (DBD):** a deceased donor for whom death has been determined by neurological criteria. Also referred to as deceased heart-beating donor.

**Donor after circulatory death (DCD):** a deceased organ donor for whom death has been determined by circulatory and respiratory criteria. Also referred to as deceased non-heart-beating donor.

**Living donor:** a living human being from whom cells, tissue or organs have been removed for the purpose of transplantation.

**Transplantation:** the transfer (engraftment) of human cells, tissues or organs from a donor to a recipient with the aim of restoring function(s) in the body. When transplantation is performed between different species (for instance, animal to human), it is referred to as xenotransplantation.

Source: Global [Glossary](#) of Terms and Definitions on Donation and Transplantation, WHO; [Newsletter Transplant](#) 2019, EDQM/Council of Europe.

## Bolstering cooperation to save lives

The issue of organ donation and transplantation is back on the political agenda. As [one of the initial health priorities](#) of the current Croatian Presidency of the Council of the EU, it was included in the 18-month '[trio](#)' programme prepared by the current and two preceding presidencies (Romania and Finland), which noted that 'cooperation in the field of transplantation and organ donation at EU level can be strengthened to save lives'. The Croatian Presidency stated in its [programme](#) that, based on Croatia's positive experience with organ donation and transplantation, it would make 'special efforts to explore the possibilities of closer and improved cooperation among Member States'.

## Organ donation and transplantation basics

Organ donation can be [defined](#) as the act of giving one or more organs (or parts thereof), without compensation, for transplantation into someone else. There are two types of organ donation: deceased donation and living donation. This means that donated organs come from either a deceased or a living donor, giving rise, respectively, to deceased-donor and living-donor transplants. There are two categories of deceased donor: those where donation takes place after brain death and those where it takes place after circulatory death (see Glossary). The objective of organ donation is to greatly enhance – or save – the life of the person who receives the transplanted organ; organ transplantation is often the [only treatment](#) for end-stage organ failure, such as liver and heart failure. Since the first successful kidney transplant in the United States in [1954](#), organ transplantation has become an established worldwide practice considered to be one of the 20th century's [exceptional medical advances](#). Demand for organ transplantation is increasing, but there are not enough organs available to meet the need. Shortage of donors is considered to be a [major limiting factor](#) in treating patients with chronic organ failure, and has resulted in long waiting lists for patients.

## Ethical considerations and fundamental human rights

There are a number of medical, legal, religious, cultural and ethical considerations associated with organ donation and transplant. In addition to being a life-saving practice, organ donation is often regarded as an expression of [human solidarity](#). It is considered to be [consistent with](#) the beliefs of [most major religions](#), including Roman Catholicism, Islam, most branches of Judaism and most Protestant faiths. According to the United Network for Organ Sharing ([UNOS](#)), research has shown that, unless a religious group has taken action to prohibit organ donation and transplantation, it is assumed that such donation is permissible: 'Donation is encouraged as a charitable act that saves or enhances life; therefore, it requires no action on the part of the religious group. Although this is a

passive approach to affirming organ and tissue donation and transplantation, it seems to be the position of a large population of the religious community'.

According to the Council of Europe's [Guide to the quality and safety of organs for transplantation](#), the handling and disposal of human organs must be carried out in a manner that shows respect for fundamental rights and for the human body. Moreover, ethical standards of all aspects of organ donation and transplantation must conform to the [Oviedo Convention](#) on Human Rights and Biomedicine and the [Additional Protocol](#) on the transplantation of organs and tissues of human origin (see the [Council of Europe](#) section below). EU Member States must also comply with the relevant EU rules (see below under [EU policy and action](#)). As the Council of Europe's guide notes, other important guidelines to be respected from an ethical point of view include the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation and the Declaration of Istanbul on organ trafficking and transplant tourism (see [World Health Organization](#)). A 2012 [review article](#) on international practices of organ donation highlights the following main points: deceased donation rates vary markedly around the world; living donation is the mainstay of transplantation in many countries; many of the unacceptable transplantation practices stem from the exploitation of vulnerable living donors; and all developments in donation should have equity, quality, and safety at their core.

## Donation and transplantation activity in Europe

The [most frequently transplanted organs](#) in the EU are kidneys (see Table 1). Other commonly transplanted organs include livers, hearts and lungs. The small bowel and pancreas can also be transplanted. New types of transplantation are meanwhile being developed all the time.

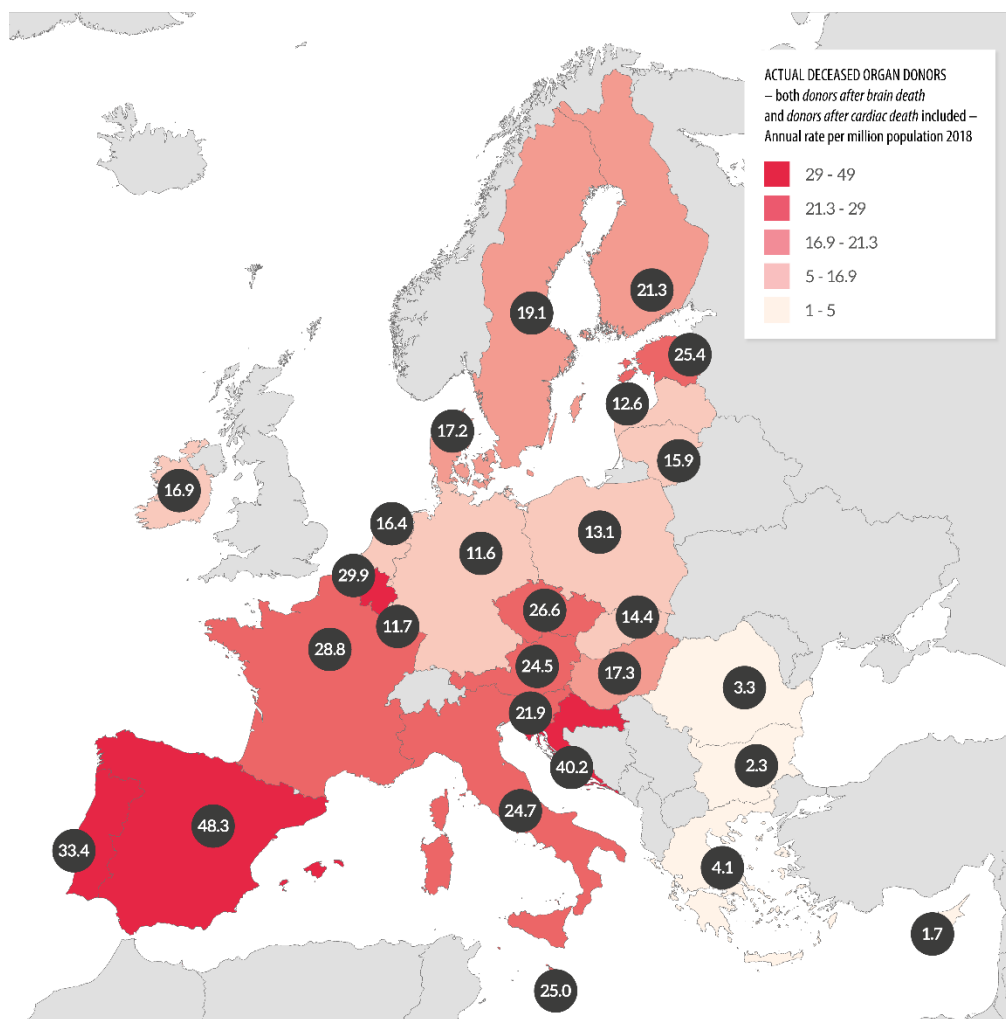
Table 1 – Number of organs transplanted in 2018 (in 28 EU countries, 509.7 million inhabitants)

Kidney	Liver	Heart	Lung	Pancreas	Small bowel	Total organs transplanted
21 227 (19.9 % from living donors)	7 940 (2.8 % from living donors)	2 287	1 980	745	42	34 221

Source: [Newsletter Transplant 2019](#), EDQM, Council of Europe.

[Nowadays in Europe](#), the main source of transplantable organs is donations from donors after brain death, ahead of those from donors after circulatory death and from living donors. According to the European Commission's 2017 [study on the uptake and impact of the EU action plan on organ donation and transplantation \(2009-2015\) in the EU Member States](#), deceased donation is a source for kidney, liver, heart, lung, pancreas and small bowel transplants. Living donation is mainly performed for kidney transplants and some liver transplants. Demand for organs exceeds the number of organs available. In 2018, over [150 000 patients](#) in Europe were registered on organ waiting lists. Organ donation rates for both deceased and living donation vary widely across the EU. In 2018, the number of actual deceased donors<sup>1</sup> ranged from 48.3 per million people in Spain, 40.2 per million in Croatia and 33.4 per million in Portugal, to 0.5 per million in Romania (see Figure 1). Living organ donation practices vary, too. In a 2013 [online survey](#), large discrepancies were found between geographical regions of Europe (eastern, Mediterranean and north-western).

Figure 1 – Actual deceased organ donors 2018 (annual rate per million population)



Data source: [Newsletter Transplant](#), EDQM, Council of Europe. Graphic by Samy Chahri, EPRS.

## Consent systems: Opting in versus opting out

EU Member States have differing national (and sometimes regional) systems enabling people to consent to donating organs after death. Under the 'opt-in' system (also called 'explicit consent' or 'informed consent' system), consent has to be given explicitly. The 'opt-out' system endorses the principle of 'presumed consent' (silence being tantamount to consent) unless a specific request for non-removal of organs for donation is made before death. There are also mixed systems. Some countries have developed donor and/or non-donor registries where citizens can record their wishes in this regard (see Table 2). In practice, [operational variations](#) exist, as the family of the deceased still plays a prominent role in the decision-making. The opt-out system is often considered to be a contributing factor to higher donation rates. Increasing organ donation by adopting an opt-out system is widely debated among the public and politicians. In this context, a recent [study](#) comparing opt-in and opt-out systems in 35 similar countries registered with the Organisation for Economic Co-operation and Development (OECD) found no significant difference in deceased-donor rates; a reduction in living-donor numbers in the opt-out countries was nevertheless observed. The authors suggest that 'other barriers to organ donation must be addressed, even in settings where consent for donation is presumed', and conclude that 'greater emphasis on education and informing the general population about the benefits of transplantation is the preferred way to achieve an increase in organ donation'. In this context, a 2016 [commentary](#) looks at whether the concept of 'nudging' deceased donation through an opt-out system constitutes a libertarian approach or manipulation.

Table 2 – Opting in versus opting out: organ donation from deceased persons in the EU

Country	Consent system	Donor registry	Non-donor registry
Austria	opt-out		x
Belgium	opt-out	*	x
Bulgaria	opt-out		x
Croatia	opt-out		x
Cyprus	opt-in	x	
Czechia	opt-out		x
Denmark	opt-in	x	x
Estonia	opt-out	x*	x*
Finland	opt-out	n/a	n/a
France	opt-out		x
Germany	opt-in		
Greece	opt-out		x
Hungary	opt-out		x
Ireland	opt-in	n/a	n/a
Italy	opt-out	x	x
Latvia	opt-out	x	x
Lithuania	opt-in	x	*
Luxembourg	opt-out	n/a	n/a
Malta	opt-out	x	
Netherlands	opt-in	x	x
Poland	opt-out		x
Portugal	opt-out		x
Romania	opt-in	x	
Slovakia	opt-out		x
Slovenia	mixed system	x	x
Spain	opt-out	x	x
Sweden	opt-out	x	x

n/a: data not available.

Note: Spain has an advanced directives registry where persons can register their desire (or otherwise) to become an organ donor after death.

\* the data regarding the existence of (non-)donor registries taken from the data source for this table differ from the results of a 2019 EDQM [survey](#).

Data source: [Guide to the quality and safety of organs for transplantation](#), EDQM, Council of Europe, 2018 (as adapted from the Commission's 2017 [study on the uptake and impact of the EU action plan](#)).

## EU public opinion on organ donation and transplantation

A 2009 [Special Eurobarometer survey](#) on behaviours and attitudes in relation to organ donation and transplantation showed that the majority of EU citizens supported organ donation, with 55 % expressing their willingness to donate their own organs after death, and 53 % willing to consent to donate organs of deceased close family members. According to the survey [report](#), distrust of the system (either the transplantation system, the consent system, and/or general social system) and fear of manipulation of the human body were the main reasons for people not wanting to donate their own organs or those of a deceased close family member. More specifically, the results showed that some 40 % of EU citizens had talked about organ donation and transplantation with their family (as explained in the report, discussion of this topic within families correlated positively with support for organ donation). Support levels for organ donation were generally higher in the countries that joined the EU before 2004 than in those that joined after 2004. Education level was also noted as a key factor influencing support for organ donation. This factor interlinked with several others, including the fact that certain age groups and regions of Europe that had more limited access to higher education tended to have lower levels of discussion, awareness and support for organ donation. Finally, financial hardship and self-described social position appeared to be a barrier to support for organ donation. Respondents who reported having difficulty paying bills were less likely to discuss organ donation with their families, or to give their consent to donation, compared to those who hardly ever experienced this difficulty. Similarly, respondents who ranked themselves lower on the social ladder were less likely to discuss this topic or to give their consent than those who gave themselves a higher social ranking.

### Denmark: from motivation to acceptability

A 2016 [survey](#) of public attitudes towards organ donation in Denmark identified a shift over the previous three decades from marked opposition to organ transplantation to strong support for it. The authors called for comparative studies in other countries to generate a better overall understanding of the conditions of acceptability that needed to be in place to ensure the long-term social robustness of organ donation.

## EU policy and action

The **European Parliament** has adopted own-initiative resolutions on various aspects of organ donation and transplantation. In its [2008 resolution](#) on policy actions at EU level, Parliament considered that the main challenge facing EU Member States with regard to organ transplantation was to reduce the organ and donor shortage. The resolution stressed that one highly effective way to increase organ availability was to provide the public with more information. It proposed establishing a 24-hour transplant hotline with a single telephone number managed by a national transplantation organisation, to provide rapid, relevant and accurate information. It also called for the introduction of a European donor card, complementary to existing national systems, and recognised the need to reduce transplant risks. In its [2012 resolution](#) on voluntary and unpaid donation of tissues and cells, Parliament stressed, among other things, the importance of non-remuneration, consent, and protection of living donors' health, underlining the need for anonymity, traceability and transparency. It called on Member States to step up their information and awareness-raising campaigns to promote the donation of tissue and cells, and to ensure the provision of clear, fair and scientifically based medical information enabling the public to make informed choices. It also asked for reinforced exchange of best practice and strengthened cooperation. In its [2013 resolution](#) on organ harvesting in China, Parliament expressed its concern at reports of systematic, state-sanctioned organ harvesting from non-consenting prisoners of conscience in the People's Republic, and called for the EU and its Member States to raise the issue in China.

The main responsibility for shaping health policies and organising and delivering care lies primarily with the EU Member States. The EU has however addressed the issue of organ donation and transplantation through legislation, an action plan and co-funded projects.

The EU can adopt measures setting high quality and safety standards for substances of human origin, such as blood, organs, tissues and cells ([Article 168](#) of the Treaty on the Functioning of the EU). [EU rules](#) on organ donation and transplantation are set out in [Directive 2010/45/EU](#) (the 'European Organs Directive'). This directive lays down the quality and safety standards for organs intended for transplantation, covering all stages of the process – from donation, procurement and handling to transplantation. [Commission Directive 2012/25/EU](#) regarding information procedures for the cross-border exchange between Member States of human organs intended for transplantation helps to implement the European Organs Directive. National [competent authorities](#) are responsible for implementing the requirements established by EU legislation. The European Commission holds regular [meetings](#) with these authorities to facilitate the exchange of best practice. Moreover, the competent authorities occasionally adopt statements on topics of common concern, such as the May 2018 [statement](#) on the proposed Global Kidney Exchange concept. As the Commission has pointed out, experience shows that some organisational models perform better than others. Identifying those elements that could be promoted at EU level would bring [European added value](#), in particular for Member States with less developed organ donation and transplantation systems. Patients that cannot be adequately treated in small Member States with a limited donor pool could thereby benefit from EU action.

The [EU action plan](#) on organ donation and transplantation (2009–2015) was designed increase organ availability; enhance the efficiency and accessibility of transplant systems, and improve the quality and safety of procedures. The Commission's 2013 [mid-term review](#) of the action plan found that the EU Member States had made good progress thus far. The main achievements related to the increased number and improved training of donor transplant coordinators, the introduction or development of living donation programmes in some Member States, and improvements in organisational models. According to the mid-term review, in the remaining period efforts would be focused on living donation programmes and on the cross-border exchange of organs.

The action plan's mid-term review reflected the December 2012 [Council conclusions](#) on organ donation and transplantation: recalling the main principles and objectives, the Council acknowledged the Member States' endeavours to meet the three challenges set by the action plan. Among other things, it welcomed the efforts made to further develop living donation programmes, the establishment of bilateral and multilateral agreements between countries, and the sharing of good practice. The Council nevertheless saw room for improvement. It underlined the importance of transparent and comprehensive communication to strengthen public trust in the value of transplant systems, and of

### Sharing best practice

Organ donation and transplant medicine is one of the areas of work of the South-Eastern Europe Health Network ([SEEHN](#)), a multi-governmental forum for regional collaboration on health, comprising Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Israel, Moldova, Montenegro, North Macedonia, Romania and Serbia. Within SEEHN, regional health development centres (RHDC) transform regional projects into long-term programmes. Headquartered in Zagreb, Croatia, the [RHDC](#) on organ donation and transplantation supports cooperation within SEEHN countries and facilitates the dissemination and exchange of good practice.

National reform efforts in three leading countries for organ donation reform – Spain, Croatia and Portugal – are described in a 2013 paper on [international approaches to organ donation reform](#). Also of note are the individual papers on the development of [donation after circulatory death](#) in Spain, and [how Spain reached 40 deceased organ donors per million population](#); the [development of the Croatian model of organ donation and transplantation](#); and [organ donation: the reality of an intensive care unit in Portugal](#).

Among the countries with the highest deceased donor rates is also Belgium, where [transplantation activities](#) were initiated in the early 1960s.

encouraging people to become organ donors after death. It invited countries to share expertise on several topics, such as expanded criteria for donors (for instance, older donors) so as to increase the number of available organs.

The Commission's 2017 [study on the uptake and impact of the EU action plan](#) found that the action plan helped countries set a shared agenda in organ donation, facilitated EU-wide collaboration, and was most effective for actions that were clearly defined and implied tangible changes in organ donation. According to the study, many Member States expressed the view that the action plan helped improve their policies on organ donation, and many considered there was a need for a new, improved action plan (for more on this see '[Looking ahead](#)' below).

In more concrete terms, the study found that the action plan resulted in a considerable increase in organ donation and transplantation in the EU over its period of implementation. Between 2008 and 2015, the number of organ donors at EU level increased from 12 000 to nearly 15 000 (a 21 % increase). This surge in donation rates resulted in 4 600 additional transplant operations (a 17 % increase). Kidney transplants accounted for 60 % of the increase, liver transplants for 24 %, and heart transplants for 11 %. Significant variations were nevertheless observed between Member States, and rates even decreased in some countries. The study also highlighted that – despite the overall progress – by the end of 2015, the demand for organs in the EU continued to outstrip supply in all countries, with thousands of people still waiting for a transplant. Furthermore, according to the study, the action plan also showed that the cross-border exchange of organs played an important role in optimising the use of the limited number of available organs. It found that, while the majority of cross-border exchanges took place within European organ exchange organisations (see text box), many Member States set up direct collaborations by means of [bilateral agreements](#) on organ exchange, such as those between Italy and Malta,<sup>2</sup> and Spain and Portugal.<sup>3</sup> Cross-border agreements enabled some countries to become more specialised in specific transplantation procedures (for instance, lung transplants for Austria and Belgium) – an expertise from which other countries could then benefit.

#### European organ exchange organisations

[Eurotransplant](#) is a non-profit international organisation that facilitates the allocation and cross-border exchange of deceased donor organs. Eight countries cooperate within Eurotransplant (Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, Netherlands and Slovenia), covering a population of roughly 137 million people. The organisation allocates more than 7 000 organs per year, and there are about 14 000 patients on waiting lists for a donor organ. In 2019, the percentage of organs exchanged cross-border was around [21.5 %](#) of all organs transplanted (see the [statistics library](#) for numbers per country).

[Scandiatransplant](#) is the organ exchange organisation for Denmark, Finland, Iceland, Norway, Sweden and Estonia (associate member). It is owned by the full member hospitals performing organ transplantation in these countries, and covers a population of approximately 28.8 million. Approximately 2 000 patients are transplanted yearly within Scandiatransplant (see also the transplantation and waiting list [figures](#)).

The South Alliance for Transplants (SAT) is [trans-national alliance](#) of south-west European countries aimed at strengthening and implementing cooperation in the field of organ, tissue and cell donation. It has five partner countries: France, Italy, Portugal, Spain, Switzerland and Czechia (observer), and covers a population of almost 202 million. SAT [accounts for](#) more than half of all organ donors and nearly half of all transplanted patients in the EU.

In the 2009 to 2015 period, several countries also started using a common organ exchange platform developed in the course of the EU-funded joint action [FOEDUS](#) (facilitating exchange of organs donated in EU Member States, 2013-2016). The FOEDUS platform makes it possible for allocation bodies to offer 'surplus organs' (organs that are difficult to match to recipients in their own country), and inversely, to get access to offers from surplus organs donated in other countries. This often concerns children. [As of February 2019](#), 13 countries had access to the exchange platform, and two countries had applied to join. The most active EU countries in terms of offering organs through the



portal are France, Spain and Italy, while the countries transplanting most organs are Italy, Czechia and France. On average, 15 organs are offered and two transplanted every month.

The EU has provided funding for several other projects in the area of organ donation and transplantation, both through the [third EU health programme](#) (2014-2020) and its predecessors, and through [Horizon 2020](#) and previous EU research framework programmes. On the initiative of the European Parliament, the EU also funded two pilot projects that ended in 2019: [EDITH](#) – focusing on treatment modalities for end-stage kidney disease, along with different organ donation and transplantation practices, and [EUDONORGAN](#) – a service contract involving training and social awareness for increasing organ donation in the EU and neighbouring countries. Other recent examples include [ELAPHARMA](#), a novel approach to organ preservation before transplantation, and [NORMOPERF](#), the development of a portable device for the [ex vivo](#) preservation and viability assessment of solid organs (kidney and liver) for transplantation based on a patented technology.

## International and European organisations

### World Health Organization

In the [area of transplantation](#), the World Health Organization (WHO) works with member states to:

- 1 provide assistance to ensure effective national oversight of [allogeneic](#) and [xenogeneic](#) transplantation activities. This would ensure accountability, traceability, and appropriate surveillance of adverse events;
- 2 increase citizens' access to safe and effective transplantation of cells, tissues and organs, and ensure ethical and technical practices;
- 3 promote international cooperation to encourage global harmonisation of technical and ethical practices in transplantation; this would include preventing the exploitation of the disadvantaged through transplant tourism and the sale of human material for transplantation;
- 4 encourage donation of human material for transplantation.

The [WHO](#) explains that transplantation of human cells, tissues or organs saves lives and restores essential functions where no alternatives of comparable effectiveness exist. The WHO also notes the major differences between countries in access to suitable transplantation, and in the level of safety, quality and efficacy of donation and transplantation. It emphasises the ethical aspects of transplantation, cautioning that transplant shortages and patients' unmet transplant needs tempt some into trafficking human body components for transplantation (see box).

#### Declaration of Istanbul

The [2008 Declaration of Istanbul](#) on organ trafficking and transplant tourism was drafted under the leadership of the Transplantation Society and the International Society of Nephrology at the end of a global summit, initiated by the World Health Organization. It sets out definitions for unethical practices, such as transplant tourism and organ trafficking, and lays down principles to guide policymakers and health professionals working in the field. The declaration was [updated in 2018](#), and now includes a more succinctly worded set of principles. For instance:

[...]

3. Trafficking in human organs and trafficking in persons for the purpose of organ removal should be prohibited and criminalised.
4. Organ donation should be a financially neutral act. [...]
7. All residents of a country should have equitable access to donation and transplant services and to organs procured from deceased donors. [...]
11. Countries should strive to achieve self-sufficiency in organ donation and transplantation.

The [WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation](#), first endorsed in 1991 and updated in 2010, urge member states, among other things, to:

- promote the development of systems for the altruistic, voluntary, non-remunerated donation of cells, tissues and organs as such from deceased and living donors, and increase public awareness and understanding of the resulting benefits ;
- oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism;
- promote a system of transparent, equitable allocation of organs, cells and tissues, guided by clinical criteria and ethical norms, as well as equitable access to transplantation services in accordance with national capacities;
- strengthen national and multinational authorities to provide oversight, organisation and coordination of donation and transplantation activities, with special attention to maximising donation from deceased donors and to protecting the health and welfare of living donors with appropriate healthcare services and long-term follow up.

The WHO operates the [Global Knowledge Base on Transplantation](#) (GKT), a source of information on organ, tissue and cell donation and transplantation for those involved in the field – from the lay public, to health professionals and health authorities. The GKT is made up of four components that are being progressively developed: activity and practices; legal framework and organisational structure; vigilance, threats and responses; and xenotransplantation. The Spanish national transplantation agency (Organización Nacional de Trasplantes, [ONT](#)) collaborates with the WHO on GKT by maintaining a global database with information on organ donation and transplantation activities derived from official sources, and on legal and organisational aspects. The database can be accessed via the [Global Observatory on Donation and Transplantation](#) (GODT) website.

## Council of Europe

In addition to being an international human rights organisation, the [Council of Europe](#) is also a leading standard-setting institution in the field of organ, tissue and cell transplantation. It has adopted legally binding texts on the topic, such as the 1997 [Oviedo Convention](#) on Human Rights and Biomedicine and the 2002 [Additional Protocol](#) on transplantation of organs and tissues of human origin to the Oviedo Convention, as well as the 2015 [Convention](#) against Trafficking in Human Organs. Its [non-legally binding texts](#) include recommendations– such as those on [xenotransplantation](#), [organ donor registries](#), [organ trafficking](#), and criteria for the [authorisation of organ transplantation facilities](#) – and resolutions, for instance, on [removal, grafting and transplantation of human substances](#), and on [establishing harmonised national living donor registries with a view to facilitating international data sharing](#). Moreover, it issues reports and other publications on the topic, such as [Ethical eye: transplants](#).

The Council of Europe's work on organ transplantation is coordinated by the European Directorate for the Quality of Medicines and Healthcare ([EDQM](#)), whose mission is: to ensure human dignity; maintain and fulfil human rights and fundamental freedoms; guarantee non-commercialisation of substances of human origin; and protect donors and recipients of organs, tissues and cells. Within the EDQM, the European Committee on Organ Transplantation, composed of internationally recognised experts, is in charge of: organ transplantation activities that promote the non-commercial donation of organs, tissue and cells; the fight against organ trafficking; and the development of ethical, quality and safety standards in the field of organs, tissues and cells. It provides [technical guides](#)

### European Day for Organ Donation and Transplantation on 10 October

The Council of Europe's EDQM organises the [European Day for Organ Donation and Transplantation](#) (EODD) every year to raise awareness of organ, tissue and cell donation as a way to improve and save lives. The EODD seeks to encourage public debate on the topic, and invite health professionals and policy-makers across Europe to reflect on the importance of this therapy. The EODD event takes place in a different country every year. In 2020, the host country is Poland.

for professionals, including on the quality and safety of both [organs for transplantation](#) and [tissues and cells for human application](#).<sup>4</sup> The Newsletter Transplant, published yearly, contains figures for organ donation and transplantation across Europe and internationally. The EDQM also issues booklets for a wider audience, such as on [donation of oocytes](#) (egg cells) or [post-transplant health](#). The EDQM's 2003 European consensus document '[Organ shortage: current status and strategies for improvement of organ donation](#)' provides a step-by-step guide to the procurement of high-quality organs from cadaveric donors, based on scientific data and international experience. The specific recommendations underline, among other things, the need for an appropriate legal framework for donation and transplantation that adequately defines brain death, the type of consent or authorisation required for organ retrieval, and the means of retrieval, ensuring traceability while maintaining confidentiality and banning organ trafficking.

## Stakeholders' views

In October 2019, a number of stakeholders from the organ donation and transplantation community submitted a [joint statement](#) (updated version – January 2020) on a shared vision for improving organ donation and transplantation to the European Commission. The statement was the main output of the 2019 thematic network on improving organ donation and transplantation, led by the European Kidney Health Alliance ([EKHA](#)). It was developed in conjunction with national competent authorities for organ donation and transplantation, transplant organisations, medical professionals and patient associations, and [endorsed](#) by co-signing organisations and Members of the European Parliament. The policy recommendations made include: i) mobilising political will to make organ donation and transplantation a priority; ii) improving legal and institutional frameworks; iii) streamlining organisation and investment in leadership at all levels; iv) allocating appropriate funds for organ donation and transplantation programmes; v) promoting education and training among all stakeholders; vi) eradicating inequities in organ donation and transplantation; vii) boosting benchmarking; and viii) leveraging research.

## Looking ahead

As noted in the Commission's 2017 [study on the uptake and impact of the EU action plan](#), many countries have agreed that future European cooperation is important to promote organ transplantation, and that EU activities should be continued. The study identified the need for a **new, improved action plan** to cover areas such as: communication; education of professionals; exchange of experiences on minorities and new population groups; end-of-life care; and research. Innovative products, such as [organoids](#) – **artificially grown organs** that mimic the properties of real organs – could become a complement to current organ transplantation to restore liver function in patients with metabolic liver disease. In the near future, organoids may even be transplanted into people to replace diseased or failing natural organs. According to the European Parliament's Science and Technology Options Assessment (STOA), producing reliable biological materials on demand through **3D bio-printing** is [an interesting future possibility](#) that might reduce our reliance on organ donors. In a possible future in which organs are 3D printed, several [ethical issues surrounding organ donation](#) would be resolved: there would be no more dilemmas regarding organ allocation or scandals due to non-transparent organ distribution by hospitals. The contested field of xenotransplantation would become obsolete. The psychological problems of patients receiving, for instance, a heart from a deceased person would no longer be an issue. Human organ smuggling would become less economically rewarding. In more realistic terms, however, there may be waiting lists for printed organs, due to limited production capacity and high costs. Moreover, one negative outcome of the feasibility of organ printing may be that motivation to donate organs would probably decline and lead to an overall worse situation in terms of [health inequalities](#) for people in need of an organ (with only those able to afford to pay for their own organs benefiting). Finally, as the study notes, before bio-printing solid organs becomes routine medical practice, the issue of whether 3D-printed organs will (or should) be patentable, and what this would mean for patients' autonomy, needs to be addressed.

## MAIN REFERENCES

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[Study on the uptake and impact of the EU action plan on organ donation and transplantation \(2009-2015\) in the EU Member States](#), European Commission, 2017.

## ENDNOTES

- <sup>1</sup> 'Actual deceased organ donors' are donors from whom at least one organ has been recovered for the purpose of transplantation (in contrast to 'utilised donors', who are donors from whom at least one organ has been transplanted).
- <sup>2</sup> From 2008 to 2010, 20 organs from Malta were transplanted in Italy.
- <sup>3</sup> In 2009, 41 organs were offered to Spain from Portugal.
- <sup>4</sup> For the downloadable versions of both publications, see the 'Main references' section.

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