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# REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

## on the implementation of 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

{SWD(2022) 376 final}

***Disclaimer: The information contained in this report is based on Member States' individual reports.***

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## 1. Introduction[1]

This report provides a summary on the implementation of Directive 2010/53/EU[2] on standards of quality and safety of human organs intended for transplantation (hereinafter referred to as "the Directive") by Member States.

The Directive provides that every three years Member States must report to the Commission on the activities undertaken and, on the experience, gained in implementing the Directive (Article 22(1)), and that the Commission must publish a report on the implementation of the Directive (Article 22(2)). A first report covered the period 2010-2014[3].

This report covers the period 2015-2021. The extended reporting period takes into account the impact of the COVID-19 pandemic for the organ donation and transplantation sector. It is based on answers from the competent authorities for Organ Donation and Transplantation from 24 Member States[4], gathered via a structured questionnaire in EUSURVEY (during the period February-April 2022). The report focuses on the changes within the Member States' competent authorities since 2015, the established donor and recipient registries, biovigilance procedures, and responses to the COVID-19 pandemic. The replies from the United Kingdom in respect of Northern Ireland[5] are summarised in separate paragraphs[6].

As further detailed in this report, the analysis of the replies from the Member States shows that overall, they did not experience difficulties with the implementation of the Directive, and the current legal framework ensures a high level of safety and quality in the organ donation and transplantation field. However, the COVID-19 pandemic created new challenges and Member States reacted quickly to ensure safety of transplantations, by following updated protocols at national level as well as the guidance provided by the European Centre for Disease Prevention and Control (ECDC).

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[1] For more information about EU actions in the field of organ donation and transplantation, please refer to the Commission dedicated webpage https://health.ec.europa.eu/blood-tissues-cells-and-organs/organs_en.

[2] 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 (OJ L 207, 6.8.2010, p. 14).

[3] https://ec.europa.eu/health/document/download/c851f24e-ea0b-4fbc-b55b-d4fc58ec61ca_en?filename=com_2016_809_en.pdf

[4] For SK, the replies were provided by the delegated body. LU, MT and RO had not replied to the questionnaire.

[5] In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of Directive 2010/53/EU, references to Member States include the United Kingdom in respect of Northern Ireland.

[6] Joint reply from Human Tissue Authority (HTA) and National Health Service Blood and Transplant (NHSBT), applicable to Northern Ireland for 2015-2021.

## 2. Designation and Obligations of the Competent Authorities [7]

Article 17 of the Directive provides that Member States shall designate one or more competent authorities (or delegated bodies) to take a series of measures, including keeping a framework for quality and safety up to date, authorising and controlling procurement organisations and transplantation centres, issuing guidance, and supervising organ exchange with other Member States and with third countries.

a. Changes in competent authorities since 2015

Since the last report on the implementation of the Directive, three Member States have experienced changes to their competent authorities for Organs, with the establishment of a new authority taking over that role (DK, EE), or a change in the organisational structure of the competent authority (BG). In addition, two Member States reported the adoption or entry into force of a new national law for Organs (EE, SI).

b. Participation in organ exchanges

All Member States reported exchanges of organs with other Member States and 20 Member States[8] reported participation in organ exchange via European organ exchange organisations (EOEO), such as Scandiatransplant and Eurotransplant, with specific agreements in place. Organ exchanges with third countries were also reported by nine Member States (AT, CY, DK, FR, IE, IT, LT, PL, SE). One Member State (IT) also referred to participation in international kidney-paired donation programmes for transplant from living donors.

Sixteen Member States (BG, CY, CZ, DE, EE, EL, ES, FR, HR, IE, IT, LT, LV, PL, SI, SK) indicated that they would be interested in increasing exchanges of organs with other Member States mostly in cases of children (14), less commonly transplanted organs (9) or cases of ABO blood types incompatibility (8). Some Member States expressed difficulties regarding other specific cases such as hyperimmunised patients (CY, IT) as well as urgent cases requiring fast response (PL). For all those specific cases, Member States consider increased exchanges as an opportunity to increase the donor pool, hence in turn increasing the probability for patients to be matched with a donor and receive a transplant. This is particularly the case for small Member States, and for difficult-to-transplant patients, or when there is no national organ transplantation programme. In the case of children, it also relates to the small number of paediatric deceased donors, or the lack of expertise and specific transplant programmes for children for some organs (again related to the small number of cases, and the difficulty to maintain a programme of the highest quality) (CZ, HR, SI, SK). One Member State (DK) stated that a potential increase of collaboration would probably and primarily be organised through the relevant EOEO.

c. Collaboration between competent authority/delegated body for Organ Donation and Transplantation and authorities and stakeholders in adjacent areas

[7] Article 17 and Chapter V of the Directive.
[8] All Member States which replied, except Belgium, Cyprus, Finland and Spain.

The majority of Member States (19[9]) reported the existence of collaboration, to various degrees, between their competent authority/delegated body for organs and authorities/stakeholders with adjacent areas of expertise (see Table 1).

| | To a great extent | To some extent | Occasionally | Never | Not applicable |
|---|---|---|---|---|---|
| Blood | 2 | 5 | 4 | 2 | 6 |
| Tissues and Cells | 6 | 4* | 3 | - | 7 |
| Medicinal Products | - | 3 | 8 | 3 | 5 |
| Medical Devices | - | 2 | 6 | 6 | 5 |
| Others | 1 | 3 | 3 | 5 | 6 |

*Of note, for Spain, the competent authority for organs is also the competent authority for Tissues and Cells, and it has collaborations with the dedicated competent authority on Assisted Human Reproduction.

***Table 1**: Existing collaborations between Member States competent authority/delegate body and authorities and stakeholders of adjacent areas of expertise.*

The collaborations are more frequent with the authorities/stakeholders in the tissues and cells area than with the ones in the blood area. Interactions with authorities/stakeholders from the medicinal products or medical devices sectors are rather occasional. Some Member States mentioned other collaborations are happening with various medical institutes (DE, IT, SI), hospitals (LV), medical agencies (EE, SE), health Ministries (DE, IT) and other bodies (BG).

The most prevalent topics of these collaborations are vigilance (14), traceability (11) and donor protection (10), but also accreditation of transplantation centres, development and maintenance of registries related to transplantation medicine, or tissue donation and banking (PL). Another Member State (SI) highlighted the topic of promotion of donation based on fundamental ethical principles, altruism and a non-profit approach, and underlined that cooperation with other competent authorities was important to ensure transparency.

Seven Member States (EL, ES, FR, IE, IT, LV, SI) expressed interest for increased collaboration with authorities/stakeholders from adjacent areas of expertise, in particular in relation to difficult cases for organ transplantation (e.g., children), the harmonisation of practices, donor protection and voluntary unpaid donation, and educational programmes and communication initiatives.

d. Northern Ireland

Competent authorities for Northern Ireland did not report any changes since 2015. Northern Ireland has an agreement with an EOEO and participates in organ exchanges with EU Member States as well as with third countries. Northern Ireland stated that there is potential to increase living donation through the UK Living Kidney Sharing Scheme, in which it participates. There is also interest for future cooperation with Ireland.

[9] All Member States which replied, except Belgium, Cyprus, Finland, Greece and Lithuania.

Regarding collaborations with other authorities and stakeholders, Northern Ireland reported extensive collaborations with authorities in tissues and cells and medicinal products sectors, whereas collaborations with authorities in the blood and medical devices areas happen to some extent. Those collaborations are mainly about vigilance, traceability and donor protection.

## 3. Donor and recipient follow-up

For some organs such as kidneys and livers, living donation is possible. This allows for a complementary source of organs. However, removing an organ from a healthy person is an invasive measure and can have medical, psychological, social and economic consequences. Hence, living donors must be carefully screened, selected and followed up, as laid down in Article 15 of the Directive. On the other hand, the follow-up of transplanted patients is left to Member States' decisions, but recital 24 of the Directive recognises that competent authorities should have a key role to play in this matter[10] and Article 17(2)(e)[11] also includes this aspect.

### a. Registries for living donors[12]

Registries for living donors exist in most of the Members States (22), but Lithuania and Sweden do not keep such registries. Since the last report, Austria and Hungary established a registry for living donors follow-up, while Estonia now uses the Scandiatransplant database. A national transplantation registry is being developed in Germany (covering both dead and living donors, and in addition to the registry on liver and kidney living donation already in place for quality assurance).

Registries vary across the Member States in their characteristics and about the organisation hosting them. While data is kept at hospital level, the hospitals also provide it to the national registries. In Spain, there can be an intermediate step of uploading data to a regional registry, before upload to the national one. The national registries are hosted either by hospitals/transplant centres (CY, IE, FI, SI), national competent authorities (AT, CZ, ES, FR, HU, PL), national transplant organisations (LV, NL, SK), health Ministries (IT, PL), national institutes (DE) or registries maintained by EOEOs such as Scandiatransplant (DK, EE) and Eurotransplant (BE). Most registries are managed by IT tools, with databases (CZ, IE, HR, PL, PT) and/or Excel sheets (BG, CY, CZ, LV). One Member State reported use of paper format documentation (SI).

Living donor follow-up intervals vary among Member States. In Austria, automated reminders are sent to the procurement centre with a request to carry out the next follow-up check on the

[10] "The competent authorities […] should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions, the collection of post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union.".

[11] "issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted.".

[12] Article 15(3) and (4).

living donor in question and to enter the data. Denmark reported that there is a delay in data entry of follow-up information. Some Member States reported that maintaining a registry for living donors improved their long-term follow-up (AT, ES, FR), including establishment of standardised examination times for them (AT) or rules for their psychological and/or psychiatric follow-up (PT).

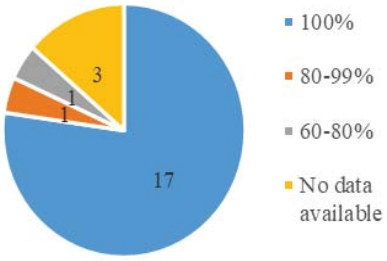


***Figure 1.*** *Repartition of Member States according to the percentage of living donors who donated an organ included in the donor registry*

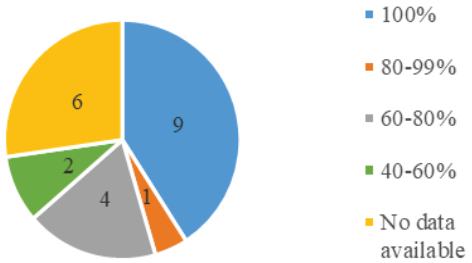


***Figure 2****. Repartition of Member States according to the percentage of living donors with followed-up data included in the registry*

The majority of Member States' registries (17) include data on 100% of the living donors, whereas Italy reports 94%, the Netherlands 67%, and three other Member States (BE, BG, DE) have no available figure (see Figure 1[13]). Follow-up data for living donors is fully recorded in nine Member States' registries (see Figure 2). In seven other Member States (DK, ES, IT, NL, PL, PT, SK), the percentage of donors with follow-up data included in the registry varies between 50 and 98%. Six Member States did not provide that data (AT, BE, BG, DE, FR, HU), but one of them highlighted that it is planning to calculate the completeness of follow-up data in 2022 (AT).

b. Registries of organ recipients

Registries of organ recipients are kept by all Member States except three (Austria, Belgium and Sweden, while Austria and Belgium have a registry for the follow-up of living donors). Half of the Member States had registries of organs recipients in place before the Directive was adopted. Five Member States (EE, HU, LV (for liver), PT, SI) established their recipient registries after 2015, while in Germany a national transplantations registry (covering both donors and organ recipients) is being developed. Most registries of organ recipients are organised in a similar way to the registries for living donors.

Registries include data mainly on patients transplanted with kidney (21), liver (18) and other organs such as heart (12), pancreas (11), lungs (10), intestine (4) and others[14] (see Figure 3). Two Member States reported the inclusion of all organ recipients in their registry (FI, FR).

[13] Member States were asked the percentage of living donors included in the registry for the year 2021 (or 2020 if no figure yet available for 2021): 11 Member States reported their data for the year 2020, other 11 for the year 2021.
[14] Registries for face (FI), vascularised tissue allografts (PL) (vascularised tissues are strictly speaking not organs, but their transplants need to be organised as if they were organs).

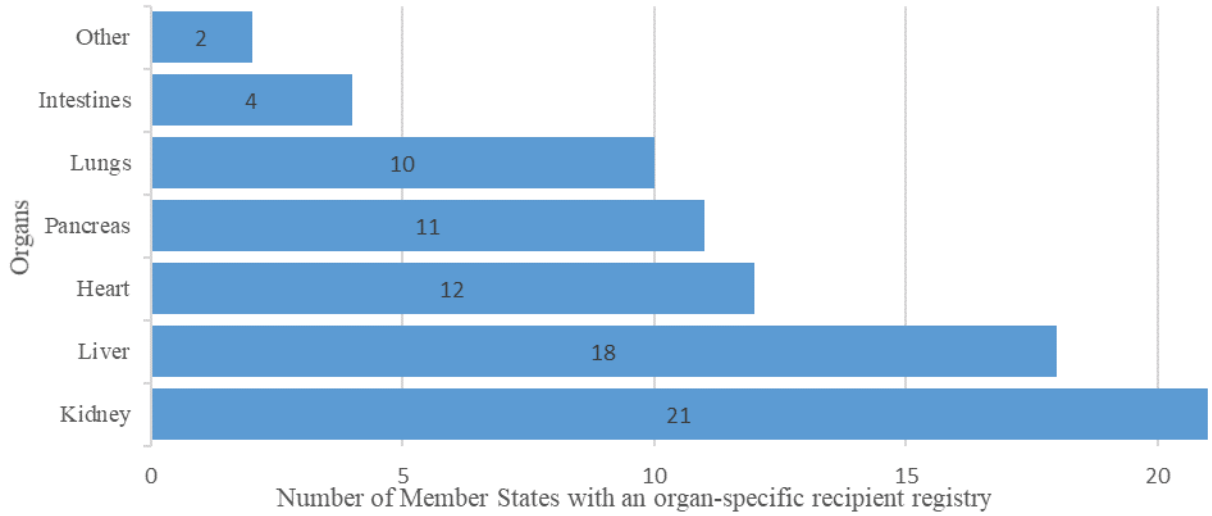


***Figure 3**. Coverage of organ recipient registries*

The majority of Member States' registries (17) include data for all recipients who received an organ during the last year for which there is complete data[15] (see Figure 4), while Lithuania reported coverage of around 22% of recipients, the Netherlands an interval of 87-96% and Italy 99.5% of organ recipients. Follow-up data for organ recipients is fully recorded in fourteen Member States' registries (see Figure 5). In five Member States (DK, FR, IT, NL, SK), the coverage is more than 50% (it can vary according to the specific organ considered); two Member States (BG, DE) did not provide the data.

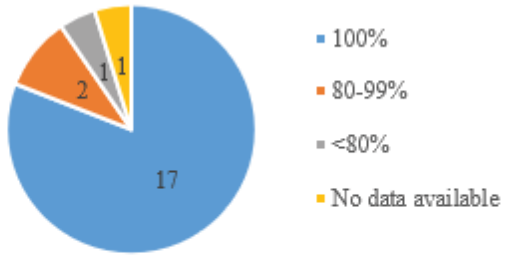


***Figure 4.** Repartition of Member States according to the percentage of organ recipients included in the registry*

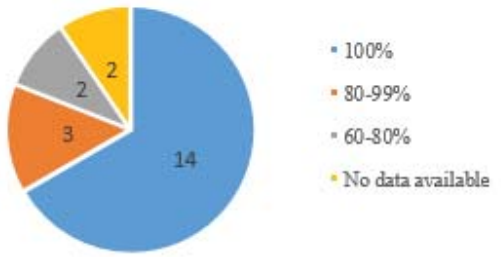


***Figure 5.** Repartition of Member States according to the percentage of organ recipients with completed followed-up data included in the registry*

c. Northern Ireland

Northern Ireland has registries for organ living donors (with requirement from the competent authority to report all living donors in a timely manner) and recipient, both hosted by a delegated

[15] Member States were asked the percentage of organ recipients included in the registry for the last year for which they have complete data (2021, otherwise 2020): 12 Member States provided percentages for the year 2021 and 9 for 2020.

body (NHSBT). Regarding living donors, since 2015, Northern Ireland has started to expand paired/pooled and altruistic donor schemes and started collecting additional information around these transplants. The registry of organ recipients covers kidney, liver, heart, lung, pancreas and intestines. Both registries include 100% of living donors and recipients, and all data on immediate follow-up (while data for follow-up after one year was not yet due).

## 4. Biovigilance[16]

Article 11 of the Directive provides that Member States shall have a system in place to report, investigate, register and transmit information, in due time, related to serious adverse events and reactions.

a. Reporting systems for information concerning serious adverse events and reactions (SARE)

The majority of Member States have specific operating procedures in place for the notification of any SARE to the Competent Authorities and to the concerned procurement organisations or transplantation centres, as well as for the notification of the management measures with regards to SARE to the Competent Authority. Since 2015, three Member States (DK, EE, FR) reported changes in their reporting systems, while another Member State (IE) reported to be in the middle of the revision of its current biovigilance system to further align it with latest guidance and best practice.

For the notification of SARE, some Member States refer to a national digital platform (FR, PT, LV), others mention published forms (BG) or a written procedure (NL).

Most systems operate at national level, with reporting exchanges between on one hand the hospitals/transplantation centres, which describe the SARE (including classification in terms of seriousness/likelihood of recurrence), take and report on immediate measures, and on the other hand, the national transplant organisation (DE, PL, SK) or the national competent authority (BG, EE, ES, FI, FR, HR, SI). In addition, in Czech Republic, Italy and Spain, there is reporting at regional level.

SARE reporting is also managed via or in close collaboration with EOEO for Member States involved in Scandiatransplant (DK, EE, FI, LT) and Eurotransplant (AT, BE, DE, HR, HU, NL, SI). For organs exchanged with other Member States, the EOEOs are launching alerts and reporting to centres and competent authorities. All the transplant centres in the Scandiatransplant area are in permanent direct contact with each other. One Member State (BE) stated that each SARE coming in from Eurotransplant is discussed in a national workgroup.

While immediate actions are taken by the transplantation centres, the next steps usually involve the competent authorities who analyse the case and ensure close coordination with relevant

[16] 23 out of 24 Member States provided answers to this section of the survey, while one Member State (SE) did not report on biovigilance, which falls under the competences of another authority which could not reply to the survey.

medical and other actors. A Member State (LT) reported that in a second step, the centre carries out an investigation and notifies the competent authority with reasons of SARE and conclusions. Another one (FR) mentioned that local biovigilance coordinator (in the centres) need to provide an annual report summarising relevant corrective measures implemented in their establishment.

The competent authorities are involved in the coordination of vigilance organisation, the developments of tools, the registration, investigation, and follow-up of each SARE, the transmission of relevant information concerning SARE in a timely manner to affected centres, including tissue establishments possibly affected (see paragraph b), the preparation of corrective measures and/or preventive measures, as well as the publication of annual vigilance reports.

In some Member States (ES, PL, IE, IT), an expert panel is also involved to review the cases, take decisions about corrective measures if needed. It can also propose measures for improving the quality of the current vigilance system. During official inspections, the operating procedures for the notification are inspected regularly (FI).

In addition, competent authorities organise training on vigilance for the biovigilance coordinators (FR). Some competent authorities also reported the publication of guidelines to help the local biovigilance coordinators in their tasks (FR), or for the reporting of SARE by donor hospitals, laboratories/pathologies, and transplant centres (DE).

b. Interconnection between the reporting system for organ transplantation and the notification system established for the transplantation of tissues and cells

In Member States where the competent authority for organs is also the competent authority for tissues and cells (BG, EE, ES, FI, FR, IT, LT, LV, PL, SI) as soon as a case is reported, possible affected tissues and cells recipients or tissue establishments are identified and notified as well as organ transplantation centres. The same biovigilance tools/systems are used for SARE for organs and tissues and cells (EE, FI, FR, SI); another Member State (IT) reported the development of a flow chart to ensure proper notification between different involved actors.

In another Member State (DE), a dedicated system has been established to allow a reliable linkage between the organ procurement organisation and the different tissue banks in case a donor donated both organs and tissues or cells. One Member State (IE) mentioned the existence of an arrangement between both functions, which will be further developed.

In some Member States, there is no automatic connection between both systems and the relevant information is communicated by email or phone (DK), exchanged between the competent delegated bodies (AT), or communicated directly to the tissue establishments by the competent authority (HU) or the delegated body for organs (SK). In other cases, the relevant information is passed between the transplantation centres and the tissue establishments directly (BE). Six Member States (CY, CZ, EL, HR, NL, PT) reported having no interconnection between the reporting systems for organ transplantation and the notification system established for the transplantation of tissues and cells.

c. Procedure of contact between competent authorities in case of SARE that can affect several Member States

Many Member States rely on the communication channels of the EOEOs they are part of, such as Eurotransplant (AT, BE, DE, HR, HU, NL, SI) and Scandiatransplant (DK, EE, FI), noting that direct contact from the competent authority to others is rarely needed, as the EOEOs have well established procedures for such events to alert the transplant centres (DK).

In other instances (CY, EL, ES, IE, IT, LT, PL, PT, SK) the communication between competent authorities happens directly via phone or email. Of note, this information can be found in the contact list on a dedicated webpage[17].

Two Member States (BG, LV) reported that in case of other Member States involved, the SARE would be reported through the Rapid Alert system for human Tissues and Cells (RATC) and another one mentioned that a system like RATC might be a useful tool for information sharing between competent authorities regarding alerts and vigilance events in the field of organs (FR). In addition, one Member State (PT) referred to specific bilateral organ exchange agreements, which define procedures for reporting SARE (in line with the requirements of Directive 2012/25/EU[18]).

One Member State explained that it does not have a specific procedure regarding vigilance information that has to be shared with competent authorities from other Member States, as the majority of organs are collected and transplanted in its own country (FR), but in necessary case, the competent authority would contact directly known counterparts in the country concerned (as was the case during the COVID-19 pandemic).

Member States are contacted in case of a SARE notified in another Member State and that might affect them, in a symmetric way.

d. Northern Ireland.

In Northern Ireland, operating procedures for the notification of SARE and of its management are in place: SARE are reported to a delegated body, which then reports to the competent authority. Regular meetings are organised between both to ensure quality and governance of the process. There is an interconnection between the reporting system for organ transplantation and the notification system for the transplantation of tissues and cells (some staff also work across the teams in charge of vigilance for organs and tissues and cell, being able to link relevant cases). In the case of SARE affecting Member States, the delegated body ensures the transmission of the relevant information to other Member States in accordance with Article 4 of Directive 2012/25/EU.

[17] http://txcontactlist.eu/

[18] Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (OJ L 275, 10.10.2012, p. 27).

## 5. Impact of the COVID-19 pandemic in the organ transplantation sector

In a statement from June 2020, EU national competent authorities on Organ Donation and Transplantation highlighted a range of needs at national and EU levels to foster recovery from the detrimental effects of COVID-19, and prepare the sector for possible future outbreaks.

a. Actions taken and challenges

Almost all Member States (except FR and SE) adapted their national procedures for organ donation and transplantation in response to the pandemic (see Figure 6). The most prevalent action concerned harmonised safety and quality protocols based on guidance such as the one from the ECDC[19]. Actions to facilitate logistics, including those required for cross-border exchange of organs and travel, and to strengthen capacities and skills of critical care professionals, donor coordinators, transplant professionals, organ procurement organisations and/or inter/national transplant organisations were also taken by many Member States as a response to the pandemic. In addition, some also took measures to support the implementation of organ preservation technologies[20] as well as to strengthen research on the effects of communicable diseases on transplantation. Six Member States implemented digital solutions for EU-wide data collection and monitoring of post-transplant outcomes and vigilance. Two Member States (ES, IT) set up specific data collection platforms for monitoring of the COVID-19 effects in the area of transplantation.

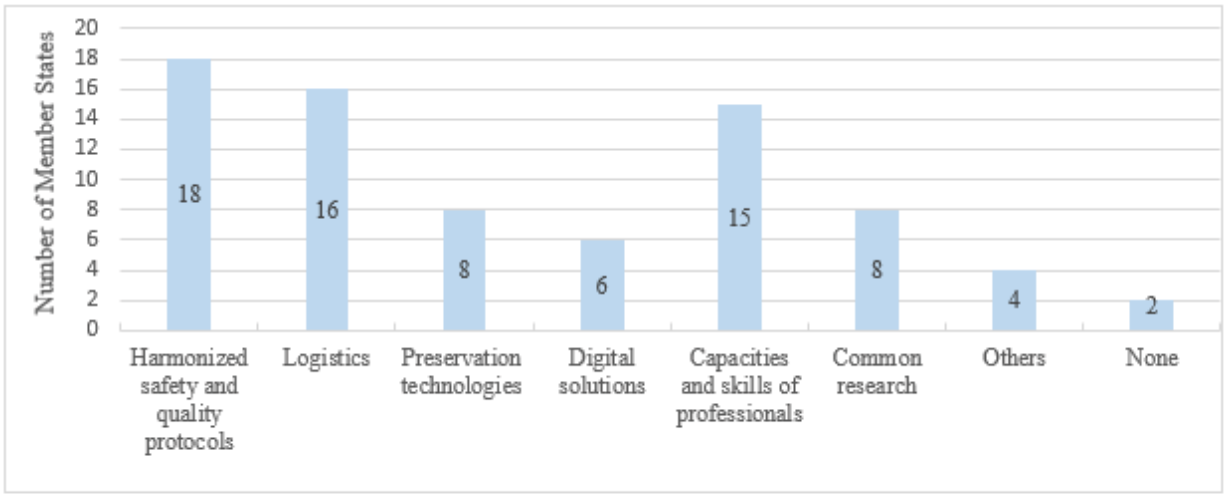


***Figure 6** Adaptation of the national procedures for organ donation and transplantation in Member States in response to the COVID-19 crisis*

[19] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin-second-update.pdf

[20] that allow longer ex-vivo time windows to facilitate transplants when logistics are more complex, e.g. in the case of local outbreaks.

One Member State (FI) noted that protocols are based on the first pandemic wave when no COVID-19 positive donors were used for organ donation, and positive recipients were not operated unless for vital indications. On the other hand, Spain and Italy reported regular updates of safety protocols and recommendations on the basis of the pandemic evolution, as well as protocols for the vaccination of transplanted patients. Italy also issued a national protocol for the use of COVID-19 positive donors. In France, an expert group provided recommendations on donor testing in order to avoid transmission of COVID-19 to the recipients, which took into account the nature of the organs (vital versus non vital organs).

In Italy, webinars for patients/transplant recipients were also organised. One Member State (PL) reported having adapted legal procedures related to accreditation of transplantation centres to online forms.

One Member State (DK) noted that countries in the Scandiatransplant area were able to test thoroughly for COVID-19 very early in the pandemic, took the associated issues into account. For that Member State, most of the transplant activities continued as usual without any sustained drop-in transplant activities. Another one (SE) reported no negative impact on the transplantations throughout the pandemic, with a record number of transplantations conducted in 2021.

Still, the pandemic created other new challenges for the competent authorities, such as problems with the organisation of the healthcare systems (intensive care unit (ICU) capacities, availability of operation theatres, exhausted staff) (reported by CY, DE, ES, HR, IE, IT, SK), or the non-homogenous spread of the pandemic (in different regions of a same country) which influenced transplant programs (IT). Rapidly changing measures and situations was also a challenge for several Member States (AT, BE, DE, FR, IE, NL, PT, SI) that required information, coordination (to establish updated procedures) and constant adaptation to new protocols. One Member State (SI) reported that many meetings between Eurotransplant members were needed, and a dedicated standing working group had to be established to monitor the most recent developments and to adapt policies and procedures where necessary. Another Member State (AT) stressed also challenges in relation to collaboration and information exchange with the national crisis management systems. Member States reported the lack of scientific information at the beginning of the pandemic (ES, FI), and the fear of transmitting the disease to transplant patients (ES). It was also challenging to test the prospective donors and obtain laboratory results in due time (CZ, FR, HU), and screenings of donors and recipients was time consuming (EL, LV.) Other challenges relate to the setting-up of COVID-19 free pathways inside hospitals (FR, IT, LV), shortages of donors (BG, CY, FR), as well as difficulties for international exchange of organs (SI), including regarding international transport logistics (EE).

Many Member States agree that all the actions taken during the pandemic (as shown in Figure 6) are still needed and relevant for their countries (DE, EE, EL, ES, IE, IT, LT, SI), while others highlighted specific ones only, in particular the necessity for harmonised safety and quality protocols based on guidance such as the one from the ECDC (BE, CY, EL, HR, PL), capacities and skills of the involved professionals (BG, CY, CZ, PT, SK), and implementation of organ preservation technologies (BG, CY, EL, HU, SK). Also, cross-border exchange of organs,

exchange of best practices and harmonisation of criteria and procedures were reported by some Member States (AT, NL, LV). Two Member States reported to welcome more frequent updates of the recommendations for testing and deferral of donors from the ECDC (EE, SE).

Two Member States (DK, FR) noted that no specific further actions are needed.

b. Priorities to mitigate the detrimental effects of COVID-19 in the organ sector, and to strengthen the sector in the long term

Member States reported two main areas that should be prioritised: (i) strengthening the capacity of intensive care services, and professionals involved in organ management, procurement and transplantation (BG, ES, IE, IT, NL, PT, SI, SK; (ii) development of guidance at EU level (including regarding COVID-19 positive donors and recipients), allowing for more harmonisation among Member States and cross-border exchanges (BE, BG, CY, EE, EL, FI, IE, LT, LV. In addition, safety protocols and emergency plans would ensure that transplant activity would not decrease in case of a new pandemic wave (HR, IT). The cooperation of scientific experts, including for comprehensive data collection, was also mentioned as a help to speed up developing evidence-based approaches (DE, FI, PT). One Member State (ES) suggested having a space to share rapid recommendations with the NCAs[21] and allow them to put national recommendations in common for comments or suggestions. Implementation of digital solutions for data collection and monitoring of post-transplant outcomes and vigilance was also mentioned (BG, EL). Some Member States also referred to other needs, in relation to: (i) the development and maintenance of an information network with cross-border partners (AT), (ii) the implementation of telemedicine tools to ensure remote follow-up of patients (IT), (iii) research (for example to exclude or prove organ specific SARS-CoV-2 transmission to maximise organ transplantation while maintaining quality and safety) (HU). Finally, the need to raise awareness of decision-makers (AT), the support for ring fencing of donation and transplantation services in Member States (IE), the close cooperation with regional transplant centres (CZ) and addressing issues of logistics for transport across Member States (BG) were also mentioned.

According to Member States, actions at EU level are best placed to address some of these priorities, in particular the development of recommendations and guidelines. EU coordination is also seen as beneficial for the exchange of national experiences and best practices, including harmonisation of donor testing measures, for the facilitation of logistics within the EU, for increasing organ exchanges (with same conditions for cross-border exchange) and increasing the donor pool, for research and exchange of scientific knowledge, which can be improved via big data platforms.

One Member State (DE) noted the necessity to become more self-sufficient at the EU level to ensure the availability of necessary resources (perfusion fluids, medical devices (testing)) and avoid shortages. It also suggested European strategies to address the challenges related to the extreme burden for the health care personal, while another refer to the need of financial support for education (SI).

[21] This has been organised via the Commission collaborative platform CIRCABC.

c. Northern Ireland

Authorities for Northern Ireland reported having taken actions (all shown in Figure 6) during the pandemic and continue to perform clinical revision of policies as knowledge and experience evolve. The authorities noted that a consistent screening programme across Member States, and the sharing of information regarding the type of test performed, is needed to ensure safe cross-border exchange of organs. They reported as challenge the capacity of critical care units, transplant units and access to ICU beds for recipients. Sharing of policies, procedures, changed practices, and data with other Member States is seen as a priority in the long term to mitigate the effects of the pandemic.

## 6. Other comments

a. Difficulties to implement or interpret the Directive

Only 2 Member States (AT, IE) reported difficulties regarding the implementation of the Directive, linked to a complex coordination involving different stakeholders, or collaboration and consolidation of different sectors and a learning phase while introducing the quality framework.

One Member State (AT) noted challenges in the interpretation of the Directive, pointing out the necessity for clear definitions and supervision. One Member State (HU) reported having more stringent rules than in the Directive, with an annual evaluation of its national organ donation and transplantation programme (publicly available). In addition, there is a hospital-level quality assurance programme for organ donation, inclusion of all discarded organs in the national organ donation registry, and quality reports of the organs at procurement and transplantation phase.

b. Relevance of the proposed revision of the legislation on blood, tissues and cells (BTC) for the organ sector[22]

Member States (DK, EE, ES, FI, FR, HR, IE, LV, NL, SI commented on the close links between organs and tissue and cells legislative frameworks (as deceased organ donors are occasionally also tissue donors), and to a lesser extent with the blood legislative framework, as they all have the same principles regarding altruistic donation. Principles and standards regarding safety and quality (including harmonisation of preventive measures in relation to the transmission of pathogens), living donor protection, non-commercialisation of the human body, traceability and biovigilance, and increased role of scientific expert bodies to draft guidelines and share knowledge were mentioned as relevant for both the organ and BTC sectors.

A clearer link between the tissues and cells and organ legislation e.g., with respect to SARE would be welcomed (DK). For another Member State (SI), transparency, traceability, quality and safety of organs, tissues and cells require the same principles and should be covered by one

[22] During the survey period (February-April), the proposed revision of the BTC legislation was under preparation : https://ec.europa.eu/health/blood-tissues-cells-and-organs/overview/revision-eu-legislation-blood-tissues-and-cells_en

legislation. Also, other Member States expressed the necessity for building communication channels for information flows between the sectors. Finally, for another Member State (IE), the revision of the BTC legislation could also lead to resources being available for training programmes provided to key personnel and teams.

## 7. Conclusions

Overall, Member States did not experience difficulties with the implementation and interpretation of the Organ Directive, in the period 2015-2021 and the current legal framework ensures safety and quality in the organ donation and transplantation field. However, the COVID-19 pandemic created new and additional challenges to Member States, which reacted in a timely manner to ensure safety of transplantations, by following updated protocols at national level as well as the guidance provided by the ECDC. EU coordination and in particular updated guidance from the ECDC were seen as essential elements during the crisis. Measures are still needed to face the pandemic, and its long-term effects, and ensure preparedness in case of another crisis.

Overall, the harmonisation of procedures in the EU is highly valued, as it can also facilitate the cross-border exchange of organs. Member States see the benefit of cross-border exchanges for increasing the donor pools and overcoming organ deficit at national level and challenges such as difficult-to-transplant patients.

Vigilance, traceability, and donor protection are the most prevalent topics for collaboration with authorities and stakeholders with adjacent areas of expertise, with interactions with the tissues and cells sector being the most relevant.

Member States have made progress in establishing their own living donor and recipient registries or rely on EOEOs for this function. There is an added value of the communication channels provided by the EOEOs in case of SARE involving other Member States.