



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

Brussels, 24 November 2021
SANTE.B.4/MA

Competent Authorities on Substances of Human Origin Expert Group (CASoHO E01718)

Meeting of the Organs Competent Authorities

24 November 2021

BY TELECONFERENCE

Summary minutes

This meeting of the Competent Authorities on Organ donation and transplantation took place on 24 November 2021. The previous meeting had taken place in April 2020 (and an informal meeting was co-organised with the German Competent Authority in October 2020).

Organs National Competent Authorities (NCA) from 20 EU Member States attended the meeting except for Bulgaria, Cyprus, Czech Republic, Greece, Luxembourg, Malta and Poland. In addition, representatives of the NCA from Norway were present. Representatives from the European Centre for Disease Control and Prevention (ECDC), the Council of Europe (EDQM), the European Health and Digital Executive Agency (HaDEA), Scandiatransplant, the European Society for Organ Transplantation (ESOT) (for point 3 of the agenda only), and the Vigilance expert sub-group (VES) also attended the meeting.

The meeting was organised and chaired by the representatives of the European Commission/DG SANTE unit B4 (Medical products: quality, safety, innovation).

1. WELCOME, INTRODUCTORY REMARKS AND ADOPTION OF THE AGENDA

The chair welcomed the participants. Introducing the meeting, the chair mentioned that the COVID-19 pandemic still causes challenges for the NCA, but also for the professionals and stakeholders active in the field. The last meetings of the group in 2020 were opportunities for the NCA to exchange experience and best practices put in place to face and mitigate the pandemic situation, and this meeting will be another opportunity for

continuing doing so. The chair explained that the meeting is also an opportunity to follow-up on the NCA statement on “Organ Donation and Transplantation and the COVID-19 pandemic”¹ (published end of June 2020).

The chair explained that the meeting would also be the opportunity for NCA to be updated on developments at the Commission level, particularly on the ongoing work on the revision of the legislation on blood, tissues and cells, and the points relevant for organs (e.g vigilance, traceability, donor protection...).

Regarding the draft agenda circulated in advance, the chair informed of the cancellation of the planned presentation from DG RTD on Horizon Europe. No other points were raised and the agenda was adopted with this change.

The participants were asked to state any conflicts of interest. No conflicts of interest were declared.

2. Impact of COVID19 on Organ donation and transplantation

2.1 Findings from the Transplant newsletter 2020

A representative from ONT presented, on behalf of ONT and the EDQM, the main findings from the recently published “Transplant newsletter”, which covers data for 2020 for EU, with UK included. The presented data indicated a total of 28 212 transplants in 2020, most of them being kidney transplants (16 890), from 9 447 deceased organ donors.

The presentation continued with an overview of the existing donation and transplantation programs in the EU Member States and the UK. This indicated that all Member States have programs for donors after brain death (DBD), and 12 had programs for donors after circulatory death (DCD). Most Member States had programs for all organs in place (kidneys (27 MS), kidney transplants from living donors (27), liver (25), heart (25), lung (23), pancreas (21)).

An overview of the number of actual deceased organ donors indicated Spain, Estonia and Croatia, and Portugal as countries with the highest numbers of donors per million population. When living donations were included in the calculation, the highest numbers of donations per million population occurred in Spain, the Netherlands, and Denmark. The number of deceased donors was reported to have decreased by 18% from 2019 to 2020, a similar decrease was also seen in the absolute number of donors and absolute number of solid organ transplantations.

The presentation further highlighted that 58 175 patients were on a waiting list for an organ transplant at the end of the year 2020. The rate was highest in Romania and lowest in Latvia. The total number of patients active on a waiting list during the year decreased by

¹ https://ec.europa.eu/health/system/files/2020-07/organs_ncastatement_covid19_en_0.pdf

12% from 2019 to 2020, and during the same timeframe the number of patients dying while on the waitlist increased by 14% (among patients waiting for an organ transplantation, there were in average 11 deaths per day across the EU and UK).

The presentation closed with a comparison of data for the years of 2020 and 2019. The overall activity had decreased markedly, although for each type of organ transplanted (except for small bowel transplantations), some Member States had increased their activity.

2.2 National experience and status: tour de table among NCA

Participants were invited to share their experience with the ongoing effects of the COVID-19 pandemic on the organ donation and transplantation sector.

- A presentation on the situation in **France** focused on the publication of recommendations as well as a series of actions taken (coordination of regional facilities, local support, interactions with learning societies, trials, publications, and contributions to weekly national health security meetings). The overall effect of the pandemic was described as a decline in inventory, procurement, and transplantation activity, for which a range of reasons was given. It was further outlined that the situation had improved, although a slight over-mortality following renal transplants was also highlighted. The speaker also invited other NCA to share their publications in a common repository.
- **Germany** reported that it did not experience a real decrease in numbers of donors, but that extreme rises in COVID-19 infections associated with capacity limits in ICUs meant having to transport patients to other parts of the country. The presentation also highlighted the efforts in organising cross-border exchanges within Eurotransplant, highlighting the importance of exchanging information and increasing communication between all countries to ensure transparency of applicable rules during the pandemic.
- **Ireland** echoed that their experience had been similar to France, while also pointing out they felt disproportionately impacted, especially in terms of heart, kidney, and liver transplants. In trying to protect access to transplants, the presentation highlighted access to ICU beds as the key concern and asked for experience from other countries on this issue.
- A presentation from **Spain** highlighted the huge impact of the 1st wave of COVID-19 cases, as well as the smaller impacts of the 2nd and 3rd waves. A protocol for COVID-19 recovered donors with persistent positive PCR tests and low viral load was presented, and good outcomes with transplants (2 kidneys, 2 livers, and 2 hearts) from these donors were reported.
- **Italy** highlighted their experience with COVID-positive donors of livers and hearts, mostly as transplants into COVID-positive recipients. They also shared data on the rate of infection in vaccinated versus unvaccinated transplant recipients.
- A presentation from **Slovenia** presented their achievements in keeping a stable number of organ transplants in 2020 and 2021 when compared to 2019, highlighting particularly their achievements in lung transplantation. The speaker explained that the lack of human

resources, particularly as regards nurses in ICUs, was the main challenge, and that no COVID-positive donors were accepted. Also, efforts were made on communication, including social media campaigns, for increased public awareness on the importance of organ donation.

The following discussion focused on different national approaches regarding the definition of full vaccination status, the consideration of CT-values for COVID-positive donors, and particularly the possibilities to perform inspections during the pandemic. On this point, different countries (Slovenia, Latvia, Germany, Portugal) responded with their experience of remote or on-site inspections.

Other countries (Italy, Estonia, Austria) reported on their experience with post-COVID lung transplants.

All participants were reminded of the possibility to share documents or publications in a dedicated share folder on CircaBC ("COVID-19 procedures and information").

3. Development of registries

3.1 Progress and plans for the further development of the kidney registries (ESOT)

A representative of the European Society for Organ Transplantation (ESOT) presented ongoing work on the design of the ESOT registry. The presentation pointed at various existing registries (the European Pancreas and Islets Transplant Registry (EPITR), the European Living Donor Registry (ELDR), the European Kidney Recipient Registry (EKRR), and the European Liver Transplantation Registry (ELTR)) that would serve as a starting point to create a platform for transplant recipients and living donors, working first for transplanted kidneys, livers, and pancreas, and later extended to include thoracic organs. It was presented that the platform would combine data from clinicians (submitted directly or via their NCA) and data from patients (submitted via a Web App). Continuing to the most recent progress, the presentation introduced Dendrite Clinical Systems as the technical partner for the development of the platform.

The presentation closed by outlining the need to establish governance, enrol centres and countries, launch the individual components of the platform, and promote its use as the next steps. More details were given firstly on the approach taken to build an inclusive mode of governance for the platform, which would include interactions between the ESOT General Assembly and the Strategic Committee as well as the Scientific Committees for the platform's individual components, and secondly on the process of enrolling centres and countries through past Joint Actions (EDITH, ELITA, and EPITA).

Some participants expressed their congratulations for the progress. The following discussion centred on the involvement of NCA in the governance of the project. It was explained that a Core Group of NCA would be first to be involved, but that a rotation was possible for further stages and that all NCAs were strongly encouraged to join, and to commit to sharing their data. The speaker outlined that this commitment would be the next

step, and that a General Assembly meeting would be called afterwards to explain the practical dimensions of data sharing.

DG SANTE also commented to underline their interest in this project being moved forward.

4. International

4.1. Council of Europe activities (EDQM)

A presentation of the European Directorate for the Quality of Medicines & Healthcare (EDQM) introduced the organisation's governance for SoHO activities as well as its current work on the 8th edition of the technical guide for the quality and safety of organs for transplantation. The presentation focused on recent developments regarding donation after circulatory death (DCDD) in Europe and introduced recently published recommendations on the development and optimization of programs for DCDD. In this recommendation document, the EDQM recommends steps for Member States regarding the implementation of DCDD programs, the development of comprehensive regulatory frameworks, training, public awareness, information, and research on this topic.

Finally, the presentation mentioned ongoing projects in four different areas:

- Gender aspects of donation and transplantation
- Reimbursement of donors in the context of prohibition of financial gain
- Timing of deceased organ donor family approach
- Benchmarking physical examination practices of organ and tissue donors.

More detail was then provided on the work against transplant-related crimes. The presentation first outlined the current global state of organ trafficking, focusing on the estimation that up to 5-10% of kidney transplants performed annually in the world (meaning 3 400 to 6 800 kidneys per year) are the result of trafficking. Based on the assumption that the involvement of healthcare professionals and facilities is necessary for transplant-related crimes (and the reporting in a 2016 TTS Ethics Committee Survey by some health professions of ethical concerns), ongoing work on the detection, prevention, combatting and reporting of transplant-related crimes by healthcare professionals was presented.

The presentation introduced the 'International Network of National Focal Points on Transplant-Related Crimes', which was established to collect data for an international database on travel for transplantation. Additionally, this network also develops national protocols, fosters interagency cooperation, professional training and outreach, and international cooperation. As an example of the data collected in the network's database, it was reported that 479 patients travelled abroad for transplantation in the 34 participating

countries since 2017. These recipients were then classified into ‘potential proper travel for transplantation’ (66%), ‘potential trafficking’ (20%) and ‘potentially impairing self-sufficiency’ (14%). It was concluded that health professionals and authorities need to prevent and combat transplant tourism.

Regarding future work, the cooperation agreement between the Commission and the EDQM (for the period 2022-2024) is planning to strengthen national donation and transplantation programs/capacity building (for NCA and delegated bodies) based on best practices for the establishment of DCDD programs and on biovigilance for organs, tissues, and cells.

4.2. Cross-over exchange IT-US

A representative of the Italian NCA (CNT) provided insights to ongoing work in organising an organ exchange scheme with US donor-recipient couples, which was initiated by the US-based organization Alliance for Paired Kidney Donation in 2018.

The presentation provided a summary of the different exchanges held on the topic and the issues of the initial proposal, including a concept based on financial incompatibility of couples, which was not acceptable. The objections of the CNT had been taken into account in a new draft proposal, stating that exchanged of kidney based on financial incompatibility is prohibited.

The new proposal also includes requirements for participating centers, specifically a minimum of 10 living transplants per year, participation in the corresponding KPD program, a well-documented experience in donor nephrectomy by minimally invasive techniques according to the current best practice, acceptance of the rules laid down in the program, and, for immunology laboratories, harmonized immunological criteria based on accreditation by the EFI or the ASHI. It was further outlined that the United Network of Organ Sharing (UNOS) had given a general green light to the terms of agreement, which would be signed by both Ministries of Health or the technical counterparts (CNT and the Alliance for Paired Donations) upon delegation by the Health Ministries. The financial coverage for three pilot cases was said to be agreed, while further financial coverage would need to be rediscussed.

The following discussion reiterated some concerns with the logistics and the possibilities for close monitoring within the program and highlighted that closer and more sustainable EU-level cooperation on the same topic might be more feasible.

A follow-up meeting on this topic was suggested, to be joined by interested NCAs to focus on the new draft agreement and the possibilities to develop a similar initiative within the EU.

5. Vigilance and surveillance

5.1. Update by the European Centre for Disease Prevention and Control (ECDC)

The ECDC provided updates about the COVID-19 pandemic, providing the most recent available data on cases and deaths in the EU/EEA. It specifically highlighted a case of proven transmission of SARS-CoV-2 through a lung transplant. In this case, the donor had shown no symptoms and tested negative on a nasopharyngeal swab obtained within 48h of procurement. Both the recipient and a thoracic surgeon involved in the transplantation procedure developed COVID-19. The speaker presented resulting recommendations, focusing on the screening of deceased donors, and mentioned reports of several liver and heart transplantations from infected donors into SARS-CoV-positive recipients.

Other updates on communicable diseases were given:

- The occurrence of 11 cases of **Ebola** in the North Kivu province of the Democratic Republic of the Congo, which has been linked back to the 2018-2020 North Kivu/Ituri outbreak, was classified as holding very low risk for citizens living in the EU/EEA. It was also reiterated that travellers returning from DRC are deferred from SoHO donation based on their malaria risk.
- An update on **West Nile Virus** presented the most recent case numbers and deaths. It also explained that discrepancies in reporting based on faulty filters had been resolved.
- The WHO Guidelines on infant feeding in areas of Zika virus transmission were presented in the context of a recent **Zika** outbreak in Kerala, India. The overall global risk level for Zika infections was described as low, although the status of Kerala as a tourist destination and the possible impact of the ongoing monsoon season were stressed. Data from the US were presented, these included 1 case within the US reported in a traveller and 26 cases in the US territories, presumed to stem from local mosquito-borne transmission. It was noted that these were diagnosed based on serologic testing rather than molecular testing, and that Zika antibodies can persist for years after infection.

The presentation closed with an outlook on SoHO activities in the ECDC planned for 2022, which will include the establishment of SoHONet expert network, the development of guidelines on Chagas disease for SoHO donations, and an expert meeting in mapping of SoHO safety preventive interventions.

5.2. Pilot of Organs SARE data collection (VES)

A representative of the Vigilance Expert Subgroup (VES) presented ongoing work on a pilot for the collection of data on serious adverse reactions or events (SARE) in the organs sector. The presentation outlined the background of the VES and the involvement of organ representatives, which started in 2018. As a basis for further discussion, the speaker presented the definitions of a serious adverse event (SAE) as given in Directives

2010/53/EC and 2012/25/EC as well as the basic principles for their classification according to the European Framework for the Evaluation of Organ Transplants (EFRETOS) and some examples of issues that would not be classified as SAE (s.a. organ lesions resulting from organ procurement or transport delays).

The second part of the presentation then focused on an ongoing pilot study for EU-wide reporting of SARE cases. This pilot aims to develop an annual report of the SARE in the organs sector in the EU which would provide an overview of European vigilance data. Participation in this pilot is voluntary. The data should be collected during the year of 2022 by the NCA wishing to participate in the pilot, with a submission by the NCA early 2023 (number of SARE cases per country in relation to the number of organ donors and transplantations, and number of transmitted diseases and number of proven and probable SAR. This should cover all post-mortal and living donors and transplant recipients). Examples of the data to be collected were presented for both living and post-mortal donations. The presentation highlighted that the main objective of the pilot was quality assurance through an objective work-up of serious undesired events in transplantation medicine, and that the main aim was to identify possible further improvements for increased patient safety.

The following discussion opened by elaborating on the links between the project and the existing Notify library. The speaker outlined that the plan was for this pilot project to supplement the data on individual cases (as provided in the Notify library) with a large-scale statistical data set. It was also highlighted that an IT system could be possible in the longer term, but not planned in the current form of this pilot. The presentation closed by reiterating that all competent authorities would be contacted to ask for their participation in due time.

6. Legislation

6.1. Update on the revision on the BTC legislation

DG SANTE presented the status of the BTC revision, focusing on the key measures to be included in the legislative proposal. The presentation also summarised the results of the stakeholder consultations.

The presentation outlined that the proposal would generally be based on an approach that includes technical guidelines developed by EDQM and ECDC, and that the scope of the future framework would be drafted to cover existing gaps (s.a. for other SoHO and for BTC processed at the bedside or during surgery). Several of the planned measures were introduced in more detail, such as a graded approach to oversight, the set-up of a BTC advisory body, and a new approach to clinical data collection for innovations. The plans for SoHO-X, the digital platform envisioned under the new proposal as a space for data

exchange between professionals, health providers, innovators, public authorities, and other stakeholders, were also elaborated on. The speaker provided more details on the discussions in relevant workshops. To close, the timeline of the revision with its planned launch of the proposal in the beginning of 2022 was presented.

Participants asked for more details on the implementation of voluntary unpaid donations, particularly the compatibility with ‘limited compensations’. It was explained that the drafting would follow the consensus emerging from the stakeholder consultations (and dedicated workshop) and the recommendations published by the Ethics Committee of the Council of Europe. Participants were also invited to reach out to their colleagues from the Tissue and Cell authorities at national level and inform them of their views regarding the revision of the BTC legislation.

6.2. Implementation of the Directive: launch of a survey

DG SANTE introduced the work on a new report on the implementation of the Organs Directive and asking NCA for their feedback on the implementation of the Directive through a survey (covering the period 2015-2021). The survey would particularly focus on:

- Changes compared to previous period regarding the NCA organisation
- Collaboration with other NCA
- Donor protection and registries
- Vigilance, traceability, reporting
- Trainings
- Impact of COVID-19 and actions taken

Participants were also informed of the planned timeline, according to which Member States would be able to comment on the draft survey, and then submit their replies to the final survey by March 2022.

7. EU-funded support

7.1. EU4Health: calls in WP 2021, and upcoming calls in WP 2022

A representative of the EU’s Health and Digital Executive Agency (HaDEA) presented the role of this new agency in improving and fostering health, protecting people from serious cross-border threats to health, making medicines available and affordable, and strengthening health systems as a basis for the EU4Health work programme 2021.

Participants were informed that a budget envelope of € 4M was foreseen for operational grants to support professional SoHO associations to improve resilience, ensure continuity of supply, increase access, safety and quality of outcome, a small part of which could be allocated to the sub-sector of organs.

It was explained that this could be a short/medium-term support to the sector via professional associations; it could also be used by the sector to prepare for more concrete targets/actions for future EU4Health work programmes.

8. Closing of the meeting

DG SANTE thanked all the attendees for their active participation during the meeting and reminded them that all presentations and associated documents would remain accessible in the CIRCABC platform.