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Harmonising activity data collection exercises in the field of tissues and cells in Europe

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CONCLUSIONS AND RECOMMENDATIONS OF THE WORKING GROUP

Harmonising Activity Data Collection Exercises in the Field of Tissues and Cells in Europe

Conclusions and recommendations of the working group

I. Objective and scope of the data collection

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
1. Member states must establish and maintain (a) national registry(ies) that is/are able to collect, at least, the identified minimum dataset.		
2. The mandatory collection of the identified minimum data set as per document 'Harmonising activity data collection exercises in the field of tissues and cells in Europe: Dataset for activity data reporting, PA/PH/TO (21) 02', will require legislative changes at EU level. However, if adopted, it would lead to important improvements in the data available both at national and EU level for transparency and biovigilance purposes, as well as to support policy decisions in relation to supply and sufficiency.		

II. Governance, responsibilities and authorisation

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
3. Governance and data collection and curation should be under the responsibility of the national Competent Authority(ies) (CA) or designated bodies.		
4. Activity data should be collected for the previous calendar year, ideally in parallel/together with the SARE exercise.		
5a. Tissue establishments must be authorised by their CA, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. This would ensure accurate and complete data reporting. Tissue establishments must report activity and biovigilance data to their CA on a yearly basis (or more frequently if so decided by the CA).	5a. Donation/collection centres must be authorised by their CA, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. This would ensure accurate and complete data reporting. Any tissue establishment collecting or storing units in a different country (e.g. cord blood units being collected in one country and	5a. MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures must have an authorisation, issued by the CA, to perform MAR procedures, and their authorisation be conditional, among other factors, on activity and biovigilance data reporting. Activities that must not be done outside an authorised tissue establishment are processing (including

In third party contracts, data reporting obligations should be included and specified. End users must ensure traceability and report data on clinical applications. Each country can decide how to organise this reporting (through tissue establishments [the same as the SARE exercise], through an established registry [e.g. ECCTR] and/or directly to the CA) and its frequency.	processed and/or stored[1] in a different one) must be authorised by their CA to do so, including the possibility of inspecting their collection and storage sites. Transplant centres must report activity and biovigilance data. Each country can decide how to organise this reporting (e.g. via EBMT and/or directly to the CA national registry(ies)) and its frequency. The CA taking part in this exercise believed it would be easier to obtain this information by having direct reporting from transplantation centres to professional societies (e.g. EBMT), instead of to the CA.	washing of sperm), preservation, storage, transport/distribution and import/export of human tissues and cells. Data must be sent by MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures to their CA on a yearly basis. Each country can decide how to organise this reporting (through tissue establishments, through (an) established registry(ies) and/or directly to the CA) and its frequency. This would ensure accurate and complete data reporting. In third party contracts, data reporting obligations should be included and specified. End users[2] must ensure traceability and report all clinical applications and SARE. Each country can decide how to organise this reporting (through tissue establishments, through (an) established registry(ies) and/or directly to the CA) and its frequency.
5b. CA must be accountable for data collection. However, the CA participating in this exercise agreed that data collection by professional societies was very valuable and could maximise the accuracy of the data. Thus, should some of the identified data be collected by professional registries, CA would have to enforce rules to ensure adequate and mandatory transmission of data from these registries to them (i.e. to their national registry(ies)) of good quality and in a timely manner. CA must qualify those registries providing data to them. This could be done through inspections. In the case of international registries, inspections could be performed by one CA (mutual recognition by other CA) or by multinational groups of inspectors, or alternatively CA could rely on qualifications performed by EU authorities.		

[1] This would not include units temporarily stored in the receiving centre for a specific patient
[2] To be understood as a healthcare practitioner who undertakes human application procedures

		5c. Clinics/healthcare professionals must be authorised by the CA to perform any of the following activities outside of a tissue establishment: • Ovarian stimulation for IUI or IVF/ICSI • Procurement of oocytes, sperm and reproductive tissues These authorisations must be conditional on reporting activity data and biovigilance (SARE) data.
		5d. MAR clinics, tissue establishments handling reproductive tissues and/or cells and independent professionals/practices performing any MAR procedures must have contracts/written agreements in place with all couples or individuals receiving MAR treatments establishing their obligation to promptly report back information about deliveries, live born children and the occurrence of any SAR (including genetic disorders in offspring when non-partner donor gametes were used). Collecting data on deliveries and live born children (as proposed in the minimum dataset) would allow assessment of the number of children born from MAR procedures in each country.
		5e. Legislation must enforce single cycle data recording.

III. Transport, distribution and import/export

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
6. When transport/distribution activities involve third parties these must be done within the framework of a SLA with a tissue establishment. It would be the responsibility of the tissue establishment to report these transport/distribution activities to the CA as part of their reporting duties. Distribution of tissues/cells to any end user must be done within the framework of a SLA that specifies the obligation of the end user to ensure traceability and report clinical applications and SARE. In the case of distribution to an end user in another EU country, in addition to the national reporting requirements, the tissue establishment which distributed the tissues/cells must be informed of any serious adverse reactions.		6. When transport/distribution activities of gametes, embryos or reproductive tissues involve third parties these must be done within the framework of a SLA with a tissue establishment. End users must report the reception of any gametes/embryos/reproductive tissues (distribution from another EU country). Transport and distribution data should be collected without making any differentiation between both types of exchanges, as the tissue establishment sending the tissues/cells cannot foresee if they will be used for clinical application (distribution) or stored or sent to a different location (transport). The interest in collecting data on distribution/transport of reproductive tissues and cells is different in the case of partner and non-partner gametes/embryos. In the case of partner gametes/embryos, these may travel in response to differences in access to care (e.g. travel to access techniques not legal or available in the country of origin), while the movement of non-partner gametes/embryos across borders is probably mainly driven by commercialisation. Having information about both types of gametes/embryos would be valuable to meet the objectives of transparency (including self-sufficiency and overreliance on certain countries) and biovigilance.

IV. Data collection by other purposes

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
7a. The collection of outcome data is very complex and requires extensive resources. Additional legislative changes should encourage detailed expanded data collection and reporting for other purposes (e.g. assessing the quality of donation and transplantation programmes, policy decisions, research), as well as detailed outcome data collection. However, this would be beyond the scope of the EU mandatory data collection exercise. On the other hand, certain registries already collect this type of data (e.g. EBMT, ECCTR). In order to improve the quality of the data and coverage of reporting bodies (i.e. to have 100% of centres reporting their outcome data), the legislation should mention the need to record outcome data, e.g. in existing registries at national level and/or registries from professional societies.		7. The collection of detailed outcome data (including efficacy, efficiency and long-term follow-up of offspring) is very complex and requires extensive resources. Further legislative changes should encourage additional data collection and reporting for other purposes (e.g. assessing the quality of donation and transplantation programmes, policy decisions, research), as well as detailed outcome data collection. However, this would be beyond the scope of the EU mandatory data collection exercise. On the other hand, certain registries already collect this type of data (e.g. ESHRE's IVF Monitoring Programme). In order to improve the quality of the data and coverage of reporting bodies (i.e. to have 100% of centres reporting their outcome data), the legislation should mention the need to record outcome data, e.g. in existing registries at national level and/or registries from professional societies. Nonetheless, basic information on outcomes (e.g. deliveries, live births from MAR procedures) is necessary for transparency and as denominators for SARE and should be collected through the mandatory dataset.
	7b. Donor centres/registries should follow up related and unrelated HPC donors. WMDA has standards for the follow-up of unrelated donors and these could be extended to related donors.	

V. Data protection and data traceability

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
8. In accordance with GDPR, patients and living donors must be informed that activity data, including at least that of the minimum dataset, will be recorded in relevant registry(ies).		
		9. Individuals undergoing MAR procedures must have a unique ID number at national level. Furthermore, couples undergoing partner procedures must be assigned a couple ID number at national level, and this couple ID number must be used for all future treatments involving the same partners.

VI. Data reporting to the EU

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
10. Following all the above specifications, the complete minimum dataset would be available from national registry(ies) and CA could therefore provide aggregated anonymised data to the EC on an annual basis, in parallel/together with the SARE exercise.		

VII. Sustainability

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
11. Collecting the information identified in the minimum dataset will involve costs and the need for additional resources at tissue establishment, national and EU levels. Thus, policy makers should provide sufficient resources to enable implementation and sustained/continued operation.		

VIII. Data dissemination at national and EU level

Replacement tissues	Haematopoietic cells	Medically assisted reproduction
12. Member states must be accountable for the data collection and its dissemination 13. This minimum data set should be made publicly available by the EC for transparency purposes, ideally disaggregated by country.		