

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

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GLOSSARY OF DEFINITIONS

Glossary of definitions for data collection on activity of tissues and cells in Europe

This glossary of definitions is intended to facilitate the completion of the activity data collection exercise for tissues and cells, 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'. In some cases, the definitions included might not be suitable for other purposes (e.g. clinical practice). If a definition is not found among the terms included in this glossary, please refer to the Council of Europe Guide to the quality and safety of tissues and cells for human application.

Application procedure: Clinical application of tissues/cells in a recipient, regardless of the number of grafts used.

Batch: A defined quantity of starting material, packaging material or product processed in one process (or series of processes) so that it can be considered to be homogeneous.

Cell product from one donor (referring to haematopoietic progenitor cells): Product obtained from one donor in the amount/dosage of haematopoietic progenitor cells needed for one patient for one transplantation procedure/episode/treatment course.

Container: Receptacle used to store tissues or cells as provided for clinical application.

Examples:

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| Musculoskeletal Tissue | One individually packaged or contained graft (e.g. one femoral head, one unit of demineralised bone, one container of bone chips, one femoral strut, one osteochondral allograft, one tendon or part of a tendon). |
| Ocular Tissue | One individually packaged or contained graft (e.g. one cornea, one piece of sclera). |
| Cardiac Tissues | One individually packaged or contained graft (e.g. one valve). |
| Vessels | One individually packaged or contained graft (e.g. one package containing one or more lengths of vessel). |
| Amniotic Membrane | One container of tissue, regardless of the area of tissue it contains. |

Couple: Two individuals who declare that they have an intimate physical relationship.

Cycle: The process (including medication or not) that leads to a unique collection of gametes (for donation or own use), to the single (at a unique time) use of gametes or to the transfer of one or more embryos in a single procedure.

Dedicated oocyte donation: A type of oocyte donation in which a specific donor is assigned to a specific recipient, who receives all of the donor's oocytes for a medically assisted reproduction treatment.

Delivery: The complete expulsion or extraction from a woman of one or more fetuses, after at least 22 completed weeks of gestational age, irrespective of whether they are live births or stillbirths. A

delivery of either a single or multiple newborn is considered as one delivery. If more than one newborn is delivered, it is often recognised as a delivery with multiple births.

Distribution: Transportation and delivery of tissues, cells and/or embryos to an organisation responsible for human application in the EU.

Donor: An individual, living or deceased, who is a source of tissue, cells or embryos for human application and for other purposes including research, from whom tissues, cells and/or embryos have been retrieved.

Embryo donation: The process by which a woman (or couple) donates embryos to enable another woman (or couple) to conceive.

End user: Person or organisation responsible for the human application of tissues and cells.

Export: Transportation and delivery of tissues and cells intended for human application to tissue establishments or organisations responsible for human application outside the EU (i.e. in a third country).

Fertility preservation: The process of saving or protecting a person's oocytes, sperm and/or, reproductive (ovarian/testicular) tissue so they can use them to try to have biological children later in life.

Import: The act of bringing tissues or cells into an EU member state from a country outside the EU (i.e. a third country) for the purpose of human application, further processing or storage.

Intra-uterine insemination (IUI): Procedure in which processed sperm cells are transferred transcervically into the uterine cavity.

Intracytoplasmic sperm injection (ICSI): A procedure in which a single spermatozoon is injected into the oocyte cytoplasm.

In vitro fertilisation (IVF): MAR procedure that involves extracorporeal fertilisation. It includes conventional *in vitro* insemination and intracytoplasmic sperm injection.

Live birth: The complete expulsion or extraction from a woman of a product of fertilisation, after 22 completed weeks of gestational age which, after such separation, breathes or shows any other evidence of life, such as heart beat, umbilical cord pulsation or definite movement of voluntary muscles, irrespective of whether the umbilical cord has been cut or the placenta is attached. A birth weight of 500 grams or more can be used if gestational age is unknown. Live births refer to the individual newborn; for example, a twin delivery represents two live births.

Medically assisted reproduction (MAR): Reproduction brought about through various interventions that include *in vitro* handling of both human oocytes and sperm, or of embryos, for the purpose of treating different forms of fertility impairment and infertility. These include, but are not limited to, ovulation induction, ovarian stimulation, ovulation triggering, intra-uterine, intracervical and intravaginal insemination with semen of husband/partner or donor, *in vitro* fertilisation, embryo transfer and intracytoplasmic sperm injection.

Non-partner procedures: Any medically assisted reproduction method that involves procurement, processing, testing and/or storage of donated human gametes, zygotes, embryos and/or reproductive

tissues of donors. Whenever donated gametes are used in a medically assisted reproduction procedure, all cycles, collection procedures and gamete units of both members of the couple should be reported under non-partner procedures.

Oocyte donation: The process by which a woman (the donor) donates oocytes to enable another woman (the recipient) to conceive as part of a medically assisted reproduction treatment.

Ovarian stimulation: Pharmacological treatment with the intention of inducing the development of ovarian follicles. Its purpose is to obtain multiple oocytes at follicular aspiration.

Partner procedures: Any medically assisted reproduction method that involves procurement, processing, testing and/or storage of human gametes, zygotes, embryos and/or reproductive tissues of couples that have an intimate physical relationship. It does not include medically assisted reproduction procedures involving any donated oocytes and/or sperm, i.e. whenever donated gametes are used in a medically assisted reproduction procedure, all cycles, collection procedures and gamete units of both members of the couple should be reported under non-partner procedures.

Release for clinical application: The act of certifying compliance of a specific tissue or cells or batch of tissues or cells with the requirements and specifications before storage.

Sperm donation: The process by which a man (the donor) donates sperm to enable a woman (the recipient) to conceive as part of a medically assisted reproduction treatment.

Split oocyte donation: A type of oocyte donation in which all the oocytes from one donor are donated for medically assisted reproduction procedures in more than one recipient.

Supernumerary oocyte (egg sharing)/supernumerary embryo donation: A type of oocyte/embryo donation in which a woman who is undergoing a medically assisted reproduction procedure donates some of her oocytes/embryos to the clinic where she is having treatment, so they can be used by another woman (or couple) for medically assisted reproduction.

Transport: The act of transferring or conveying of tissues and cells from one place to another within one organisation or between facilities. It may include transport between tissue establishments within the same country or to another EU member state for further processing or storage.