

Global Glossary of Terms and Definitions on Donation and Transplantation

Geneva, November 2009

Global Glossary of terms and definitions on donation and transplantation

The lack of a globally recognized terminology and definitions as well as the need for a uniform collection of data and information for the Global Database on Donation and Transplantation (¹), triggered off the unification of terms and basic definitions on cell, tissue and organ donation and transplantation in order to create a Global Glossary. The aim of this Glossary is to clarify communication in the area of donation and transplantation, whether for the lay public or for technical, clinical, legal or ethical purposes.

In 2007 WHO, together with The Transplantation Society (TTS), and the Organizacion Nacional de Trasplantes (ONT) in Spain, initiated a harmonization process and held the "Data Harmonization on Transplantation Activities and Outcomes: Editorial Group for a Global Glossary Meeting", gathering together experts from the six WHO Regions, professionals and representatives of government authorities.

Existing official definitions were selected whenever deemed appropriate. Furthermore, the Editorial Group either adapted existing definitions or produced new definitions.

A draft resulting from this process was posted on the WHO Website for several months for comments.

The present document "Global Glossary on Donation and Transplantation" is the outcome of this process. It is anticipated that the Glossary will be completed and adapted with the progress of global consensus. Users are invited to refer to the WHO/transplantation website and to indicate the date of consultation if they quote the Glossary. Suggestions and comments are welcome and should be sent to transplantation@who.int.

 $(^{1})$ The Global Observatory on Donation and Transplantation is a collaborative effort of the World Health Organization and the Organization Nacional de Trasplantes (ONT) of Spain.

The World Health Organization is grateful to the Spanish Government and The Transplantation Society for their support.

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¹ In all definitions in the Glossary the use of "cells, tissues and /or organs" has been standardized, whenever was applicable.

Glos<u>sary of Terms and Definitions</u>

1. Actual Organ Donor

Deceased or living person from whom at least one solid organ or part of it has been recovered for the purpose of transplantation.

Allocation is the assignment of human cells, tissues and organs to a transplant candidate, based on a set of

2. Allocation

rules.

3. Allogeneic

Cells, tissues and organs donated by one person for transplantation to another person. Modified from First Global Consultation on Regulatory Requirements for Human Cells and Tissues

4. Amniotic membrane

A thin membrane surrounding the fetus during pregnancy.

The smallest transplantable and functional unit of living organisms.

Preparation of retrieved cells to make them suitable for transplantation.

5. Bank

See Tissue Establishment

6. Bone Marrow

7. Brain Death

8. Cardiac Death

Tissue at the center of large bones. It is the place where new blood cells are produced. Bone marrow contains two types of stem cells: haematopoietic (which can produce blood cells) and stromal (which can produce fat, cartilage and bone).

Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time.

Glossary of UNOS

Death resulting from the irreversible cessation of circulatory and respiratory function; an individual who is declared dead by circulatory and respiratory criteria may donate tissues and organs for transplantation. Editorial Group

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12. Compatibility testing

Testing for the presence or absence of recipient antibodies to HLA antigens and to blood group antigens present on the transplant cells, tissues or organs. Editorial Group

Formal standardized documentation of death. Refer to both cardiac death and brain death.

Editorial Group

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EUROCET

Editorial Group

10. Cell Manipulation

9. Cells

11. Certification of Death

13. Confidentiality

14. Consent to donation

Legally valid permission for removal of human cells, tissues and organs for transplantation.

Recognized exceptions in the medical context may be justified by a country's laws.

15. Cord blood

Haematopoietic progenitor cells collected from placental vessels and umbilical cord blood vessels after the umbilical cord is clamped and/or severed. Extracted from JACIE standars

Regards the treatment of information an individual has disclosed in a relationship of trust. This relationship implies the expectation that the disclosed information will not be divulged without prior permission.

16. Cord blood Bank

Is a facility or organization regulated by authorities, where haematopoietic progenitor cells collected from the placental and umbilical cord blood vessels are processed, cryopreserved, and / or stored. It may also be responsible for procurement, testing or distribution. Modified from JACIE standards

17. Cornea

The dome-shaped window structure covering the front of the eye.

18. Culture Expansion

In vitro, proliferation of retrieved cells for the purpose of transplantation.

19. Death Diagnosis

Confirmation of death from evidence acquired through clinical investigation / examination, meeting criteria of brain or cardiac death.

20. Deceased Donor

A human being declared, by established medical criteria, to be dead and from whom cells, tissues or organs were recovered for the purpose of transplantation. The possible medical criteria are:

- Deceased Heart Beating Donor (Donor after Brain Death): Is a donor who was declared dead and diagnosed by means of neurological criteria.

- Deceased Non-Heart Beating Donor (Donor after Cardiac Death) = Non-heart beating donor (NHBD): Is a donor who was declared dead and diagnosed by means of cardio-pulmonary criteria.

Editorial Group

21. Distribution

22. Domino Donor

Transportation and delivery of cells, tissues or organs intended for human applications, after they have been allocated.

A procedure in which an organ is removed from one transplant candidate and immediately transplanted into

A person who by receiving an organ transplant donates the removed organ to another recipient.

Modified from EU Directive 2004

Editorial Group

23. Domino Transplant

24. Donation

Donating human cells, tissues or organs intended for human applications.

a second patient, with the first patient receiving a new organ from a deceased donor.

Editorial Group

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Modified from EUROCET

Editorial Group

Editorial Group

Modified from EU Directive 2004

Glossary of UNOS

25. Donation processing registries

26. **Donor**

transplantation.

27. Donor evaluation

The procedure of determining the suitability of a potential donor, living or deceased, to donate.

A human being, living or deceased, who is a source of cells, tissues or organs for the purpose of

The process and critical pathways used to medically care for donors in order to keep their organs viable until

28. Donor maintenance

organ recovery can occur.

29. Donor safety

A minimization of living donor complications or adverse reactions related to donation

30. Encephalic Death

Refer to Brain Death definition

31. Ethics Committee

Committee charged with considering ethical issues related to the process of organ procurement, distribution, transplantation, pre and post donation and transplantation care and research for cells, tissues and organs. Such a committee should be at a national level, but can also be at a regional or local level.

Legally valid permission for removal of human cells, tissues and organs for transplantation, Otherwise known

must be according local (exporting country) laws, international laws and conventions and receiving country

Subsequent examinations of a patient, living donor or recipient, for the purpose of monitoring the results of the donation or transplantation, care maintenance and initiating post-donation or post-transplantation

A repository of data collected on cell, tissue and organ donors and /or transplant recipients for the purpose of

outcome assessment, quality assurance, health care organization, research and surveillance.

32. Explicit consent

33. Exported / Export

Human bodies, body parts, cells, tissues or organs for human application, legally procured inside of the national boundary and transported to another country where it is to be further processed or used. Export

34. Follow up

interventions.

as "opting in".

laws.

35. Follow up Registry

36. General National Transplantation Manager

The person responsible for the policy development, management and harmonization of the process of donation & transplantation at a national level of cells, tissues and/or organs. Such responsibilities could also include promotion, public education, waiting list management, quality control and standards of care and follow-up registries.

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A repository of data collected of aspects concerning to the donation process and activities.

Modified from FDA. Human Tissue Intended For Transplantation.

Editorial Group

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Adapted from UNOS

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37. Grafted

Refer to Transplantation definition

38. Haematopoietic Progenitor Cells (HPC)

Include primitive pluripotent haematopoietic cells capable of self-renewal as well as maturation into any of the haematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified, regardless of tissue source.

Extracted from JACIE standards

39. Heart Beating Donor

Refers to Brain Death definition

40. Heart Valve

Valves between the chambers of the heart and between the heart and blood vessels around the heart which maintain the unidirectional flow of blood (Aortic Valve, Pulmonary Valve, Mitral Valve and Tricuspid Valve).

EUROCET

41. Human cells and tissues for transplantation (HCTT):

Means articles containing or consisting of human cells and/or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCTTs include, but are not limited to musculoskeletal tissue (bone, cartilage, meniscus), skin, soft tissue (tendons, ligaments, nerves, dura mater, fascia lata and amniotic membrane), cardiovascular tissue (heart valves, arteries and veins), ocular tissue (corneas and sclera), bone marrow and haematopoietic stem/progenitor cells derived from peripheral and cord blood and stem cells of any tissue, and reproductive cells/tissues. The following articles are not considered HCTTs:

(1)Vascularised human organs for transplantation;

- (2) Whole blood or blood components or blood derivative products;
- (3) Secreted or extracted human products, specifically, milk, collagen, and cell factors;
- (4) Cells, tissues, and organs derived from animals other than humans.

Adapted and Modified from FDA. Cells, Tissues and Cellular and Tissue-Based Products.

42. Imported / Import

Human bodies, body parts, cells, tissues and organs for human application, legally procured outside of the national boundary to which it has been transported for use. Importation must be according local (receiving country) laws, international laws and conventions and supplying country laws.

Editorial Group

43. Incompetent person

An individual who is unable to make legally valid decisions or is deprived of his/her capacity to decide and/ or to understand the implications of his/her actions (e.g a minor or an individual legally declared unable to manage their own affairs).

Editorial Group

44. Informed Consent

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

Glossary of UNOS

45. Irreversible cessation of brain / brain function

Refer to Brain Death definition

46. Irreversible cessation of cardio respiratory function

Refer to Cardiac Death definition

47. Living Donor

A living human being from whom cells, tissues or organs have been removed for the purpose of transplantation. A Living Donor has one of the following three possible relationships with the recipient: A/ Related:

A1/ Genetically Related:

1st Degree Genetic Relative: Parent, Sibling, Offspring 2nd Degree genetic relative, e.g. grandparent, grandchild, aunt, uncle, niece, nephew, Other than 1st or 2nd degree genetically related, for example cousin A2/ Emotionally Related: Spouse (if not genetically related); in-laws; Adopted; Friend

B/ Unrelated = Non Related: Not Genetically or Emotionally Related

48. Musculoskeletal

Tissues which are part of the skeletal and/or muscular system such as muscles, bones, cartilage, tendons and ligaments which function in support and movement of the body.

Modified from EUROCET

Editorial Group

49. Non-Heart Beating Donor

Refers to Cardiac Death definition

50. Not for profit = Non - profit

Qualifies an organization whose primary objective is to support an issue or matter of private interest or public concern motivated by non-commercial purposes, without concern for monetary profit. Generic definition

vascularisation and capacity to develop physiological functions with an important level of autonomy.

Differentiated and vital part of the human body, formed by different tissues, that maintains its structure,

Deceased person without absolute medical contraindications with brain death or cardiac death diagnosis

51. Organ

after death.

initiated or completed.

52. Potential Deceased Donor

53. Potential deceased donor identification

The system and processes for identification of potential deceased donors.

54. Pre-stated acceptance / Permission / Authorisation

55. Pre-stated refusal (of permission for removal of Human Cells, Tissues and Organs)

Legal and officially recorded statement of acceptance from the individual to donate cells, tissues and organs

Legal and officially recorded statement of refusal to donate cells, tissues and organs after death.

absence of individual pre-stated refusal of permission. Otherwise known as "opting out".

56. Presumed consent

57. Processing

All operations involved in the preparation, manipulation, preservation and packaging of cells or tissues intended for human applications.

Legally valid presumption of permission for removal of cells, tissues and organs for transplantation, in the

EU Directive 2004

Editorial Group

EU Directive 2004

Modified from DOPKI

Editorial Group

Editorial Group

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58. Procurement

59. Recipient

principle, or law.

60. Regulatory oversight

maintenance and retrieval of cells, tissues or organs.

61. Retrieval or recoverv

62. Serious Adverse Event

63. Serious Adverse Reaction

results in, or prolongs, hospitalization or morbidity.

Strips of skin for grafting and procured as partial or full thickness.

Any untoward occurrence associated with the procurement, testing, processing, storage, distribution, transplantation procedure itself or post-transplantation management procedure of cells, tissues and organs that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalization or morbidity. Modified from EU Directive 2004

An unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement, the transplantation procedure itself or post-transplantation management procedure in the human application of cells, tissues and organs that is fatal, life-threatening, disabling, incapacitating or which

The process that includes donor identification, evaluation, obtaining consent for donation, donor

The management or supervision of a group by an outside body in order to control or direct according to rule,

The human being into whom allogeneic human cells, tissues or organs were transplanted.

Modified from EU Directive 2004

65. Split-liver

64. Skin

A split liver transplant is defined when a donor liver is divided into parts and transplanted into more than one recipient.

Modified from UNOS

66. Storage

The maintenance of donor cells, tissues or organs under appropriate controlled conditions until transplantation or disposal.

Modified from EU Directive 2004

67. Surveillance

The systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary.

International Health Regulations 2005

68. Surveillance System (for Human Cells, Tissues and Organs for transplantation)

An established process at a local, regional or national level for the reporting of serious adverse events, serious adverse reactions or complications related to donation and transplantation of cells, tissues and organs.

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69. Technical Committees / Advisory Boards

Specialized professional committees providing recommendations of any aspect of the donation and transplantation process of cells, tissues and organs.

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The procedure of removing cells, tissues or organs from a donor for the purpose of transplantation. Editorial Group

EUROCET

70. Time on Waiting List

The time from placement on the Waiting List for a transplant until the date of reporting (of a transplant) or until removal (from the Waiting List).

71. Tissue

73. Traceability

All constituent parts of the human body formed by cells.

72. Tissue Establishment

A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells.

The ability of an authorized organization to identify and locate all cells, tissues or organs from all specific donors at any time after donation, linked to all specific recipients and vice versa from recipients to donors. This traceability applies to any step of procurement, allocation, processing, including processing agents,

EU Directive 2004

EU Directive 2004

Editorial Group

74. Trafficking (Cells, tissues or organs)

storage, distribution or disposal at any time after donation.

The recruitment, transport, transfer, harboring or receipt of living or deceased persons or their cells, tissues or organs, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of cells, tissues and organs for transplantation.

Modified from The Declaration of Istanbul

75. Transplant Commercialism

Is a policy or practice in which cells, tissues or organs are treated as a commodity, including by being bought or sold or used for material gain.

Modified from The Declaration of Istanbul

76. Transplant Tourism

Travel for transplantation when it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplant to patients from outside a country undermine the country's ability to provide transplant services for its own population.

Declaration of Istanbul

77. Transplantation

transplantation purposes.

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, e.g. animal to human, it is named Xenotransplantation.

Is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for

Editorial Group

78. Travel for transplantation

79. Urgency

A measure or indicator of a candidate's relative ability to wait for transplantation compared to that of other candidates.

80. Vascular Tissues

Referring to blood vessels.

Editorial Group

Lancinal Croap

Declaration of Istanbul

Modified from UNOS

81. Waiting List (WL)

The list of candidates registered to receive a human cell, tissue and organ transplant.

Editorial group

82. Waiting List Management

A system (or method) for maintaining a waiting list accuracy and currency, protecting the privacy and confidentiality of patients in the Waiting List.

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