



**Data Harmonization on Transplantation Activities
and Outcomes:**

Editorial Group for a Global Glossary

Geneva, 7-8 June 2007

Report

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

EXECUTIVE SUMMARY

The intention of this report is to provide an overview of the issues discussed and conclusions as a result of the Data Harmonization on Transplantation Activities and Outcomes: Editorial Group for a Global Glossary Meeting, which was organized by WHO in collaboration with The Transplantation Society and the Spanish Organization of Transplants.

The collection of data and information in the Global Database on Donation and Transplantation (GDDT) is being made possible by using a unified global questionnaire. Nevertheless there was a need to work as well for the unification of terms and basic definitions on donation and transplantation and create a global glossary. This glossary would have an impact on the collection and analysis of data, which would improve the results.

As part of the harmonization process to prepare a global glossary, this meeting had the aim of achieving consensus on basic definitions on donation and transplantation.

A document was prepared, including an extensive revision of definitions, coming from different but recognized sources, which was used as a baseline document.

The meeting group, called the Editorial Group, had the opportunity to review some terms and definitions and achieve consensus on them. During the sessions, there were some definitions which led to deep discussions, especially those with ethical and legal connotations, such as living and deceased donor, consent, legally non-competent person, trafficking and transplant tourism. Some of them were revised again after the meeting and even if agreed, they were modified after further consultation.

The definitions agreed during the meeting are presented in the body of this report with some comments whenever necessary. At the end of the meeting it was clear that more work had to be done. The attached document of this report presents all proposed definitions after revision and further consultation by the Editorial Group.

OPENING SESSION

Dr Steffen Groth, Director of the Essential Health Technologies Department in WHO, welcomed participants to the Data Harmonization on Transplantation Activities and Outcomes: Editorial Group for a Global Glossary Meeting.

He remarked on the importance of harmonization of terms and definitions and made references to the TTS New Key Opinion Leader Meeting on harmonization of registries which took place before the meeting. Dr Groth acknowledged the TTS and the National Organization of Transplants (ONT) of Spain for their collaboration and support in organizing this meeting.

He expressed his hope for the meeting to produce a globally-agreed baseline to reach a common glossary of definitions on donation and transplantation.

Dr Frank Delmonico (TTS) and Dr Beatriz Dominguez-Gil (ONT) were elected to Co-Chair the meeting and Mr Peter Feldman (TTS) as Rapporteur.

Dr Groth stressed that this was an informal and flexible meeting.

INTRODUCTION

Ms Mar Carmona provided an overview of the background, the sources used to elaborate the background document to work on, and explained what was expected as result of the meeting.

BACKGROUND

WHO, in collaboration with ONT, are working on the Global Database on Donation and Transplantation (GDDT), which compiles information on donation and transplantation activities, legal frameworks and organizational systems. To collect all these pieces of information from every country, a common questionnaire is being used.

In the concrete case of the global questionnaire, it was seen that using it for the collection of data was not enough to obtain harmonized responses. There was also a need for common understanding and interpretation of terms and definitions that would lead to the production of reliable results.

As part of the harmonization process of terms and definitions on donation and transplantation, it was decided to create an agreed upon global glossary which could be included together with the global questionnaire.

The questionnaire was taken as a good base to seek for terms to define.

OBJECTIVE

Ms Carmona explained that the aim of the meeting was to agree on terms and definitions on donation and transplantation, to be used globally.

SOURCES

With regard to the material provided for the meeting as a starting working document, Ms Carmona gave some examples of the sources for the terms and definitions proposed. A search was made and the following sources were used:

- Glossary of UNOS
- European Directive
- Canadian Standards Association
- US Food and drug Administration (FDA)
- Clinical Research Office
- European projects such as DOPKI, EURO CET and ALLIANCE-O
- First Global Consultation on Regulatory Requirements For Human Cells and Tissue for Transplantation
- IAEA. International Standards on Tissue Banks
- International Society for Stem Cells Research
- JACIE Standards
- National Program of Marrow Donor; etc.

EXPECTED OUTCOMES AND SCOPE

Ms Carmona said that the expected outcome of the meeting had the target of agreeing on definitions for certain proposed terms.

It was clear that a global glossary of donation and transplantation definitions would help to compile harmonized responses and would improve the interpretation of data of the GDDT.

It was noted that the scope of the meeting was intended to cover basic definitions, avoiding adjectives and complexity.

The group of the meeting was called Editorial Group.

MEETING SESSIONS

The Editorial Group used recognized definitions from different sources whenever possible. Nevertheless, in some cases it was necessary to include small modifications in the original source, which was reflected also in the source: “Modified from....”. When the definition was created by the Editorial Group, the source was indicated as: Editorial Group.

During the second day of the meeting participants split into small groups to review groups of definitions and then the whole group reviewed the proposals.

Although agreed in the meeting, a few definitions were reviewed and slightly modified after further consultation.

Explanations are provided when necessary for those definitions which created concern or discussion. The terms agreed by the Editorial Group during the meeting are as follows.

DISCUSSIONS

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

Organs and cells were added to the original definition (Source: FDA, Cells, Tissue and Cellular and Tissue-Based Products).

Living Donor: A Living Donor is 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:

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

Emotionally Related (examples include)

Spouse (if not genetically related)

In-laws

Adopted

Friend

Unrelated

Not Genetically or Emotionally Related

This definition of the living donor was elaborated by the Editorial Group. However it was seen during the process after the meeting that it could be reclassified into two bigger groups: Related and Unrelated. Related would include Genetically and Emotionally.

Deceased Donor: A Deceased Donor is a human being legally 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): A Deceased Heart-Beating Donor is a donor who was legally declared dead by neurological criteria.

Deceased Non-Heart-Beating Donor (Donor after Cardiac Death): Deceased Non-Heart-Beating donor is a donor who was legally declared dead by cardio-pulmonary criteria.

The original definition (Source: EUROCET) referred to be declared dead according to national regulations. Nevertheless it raised the discussion to change those terms by legally. Then, after further consultation, the definition was altered again. The word "legally" was removed because it was seen that was a "clinical" definition, not legal. Some countries may have regulations but not law, and following this definition as it stays, they would not fulfil it. Domino Donor: A person who by receiving an organ transplant donates the removed organ to another recipient.

Procurement: The process that includes donor identification, evaluation, obtaining consent for donation, donor maintenance and retrieval of organs, tissues or cells.

The Editorial Group considered the addition of evaluation, consent for donation and maintenance to the original definition and also applies to organs (Source: Aide-Mémoire. Human Cell and Tissue for Transplantation).

Retrieval (Recovery): The procedure of removing organs, tissues or cells from a donor.

It was suggested to say recovery as well.

Cross Match Compatibility for Organ Transplantation: Absence of recipient antibodies to HLA antigens present on the transplant organ.

Blood group compatibility for Organ Transplantation: Absence of recipient antibodies to blood group antigens present on the transplant organ.

Although both definitions were agreed in the meeting, after further consultation they merged into one term: Compatibility Testing. Those aspects do not apply only to organs but also to tissues and cells. It was also seen that the questionnaire had necessarily to include both cross match and blood group compatibility. Note was well taken in order to make the proper changes.

Processing of Tissues or Cells: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human application.

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

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

The Editorial Group considered the addition of the last part "after they have been allocated" to the original definition (Source: Directive 2004/23/EC of the European Parliament of the Council of Europe).

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

Wait List (WL): The list of candidates registered to receive an organ, tissue or cell transplant

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)

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

Due to the legal and also ethical complexity of this term, it was seen that this general definition could be applicable for those involved, i.e. living and/or deceased, next of kin, etc.

Presumed Consent: Legally valid presumption of permission for removal of organs, cells and tissues for transplantation, in the absence of individual pre-stated refusal of permission. Otherwise known as "opting out" law legislation.

Pre-stated Refusal of Permission for Removal of Organs, Cells and Tissues: Legal and officially recorded statement of refusal to donate organs, cells and tissues after death.

Pre-stated Acceptance: Legal and officially recorded statement of acceptance to donate organs, cells and tissues after death.

This definition was agreed by the Editorial Group during the meeting. Nevertheless it was reviewed after consultation and included "of acceptance from the individual".

Explicit Consent: Legally valid pre-stated individual permission for the removal of organs, cells and tissues for transplantation, otherwise known as "opting in" law.

Although agreed by the Editorial Group, it was modified after further consultation. "Pre-stated individual" was removed.

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.

Legally Non-Competent Person: An individual unable to provide legally valid permission for the removal of organs, cells and tissues for transplantation, (e.g., a minor or an individual legally declared unable to manage their own affairs).

This definition was agreed by the Editorial Group; however it was reviewed and modified after. This term was seen as a legal term and not clinical. Due to the legal and ethical connotations implied, it was suggested to ask some of the departments within WHO for a universal definition. After further consultation the term was changed to “Incompetent Person”, which is recognized legally.

Commercialization (organ, tissues, cells): Handling of Organs, Cells or Tissues for financial profit. Commerce may be conducted legally or illegally.

Trafficking (organ, tissues, cells):

The discussion of this definition led to the use of the United Nations definition of Trafficking in Persons. Although it addresses organs, it is important to note that trafficking refers to not only organs but also to tissues and cells.

55/25 United Nations Convention against Transnational Organized Crime

Annex II Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime

Article 3

The definition of trafficking “Trafficking in Persons” shall mean the recruitment, transportation, transfer, harbouring or receipt of persons, 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 or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of exploitation. Exploitation shall include, at a minimum, the exploitation of the prostitution of others or other forms of sexual exploitation, forced labour or services, slavery or practices similar to slavery, servitude or the removal of organs; (b) The consent of a victim of trafficking in persons to the intended exploitation set forth in subparagraph (a) of this article shall be irrelevant where any of the means set forth in subparagraph (a) have been used; (c) The recruitment, transportation, transfer, harbouring or receipt of a child for the purpose of exploitation shall be considered “trafficking in persons” even if this does not involve any of the means set forth in subparagraph (a) of this article; (d) “Child” shall mean any person under eighteen years of age.

Transplant Tourism: The travel of prospective transplant recipients or donors across national borders and involving the trafficking of organs, tissues or cells. The travelling of patients or donors across national borders should not be understood as transplant tourism, when organs are not trafficked. Travelling of prospective transplant recipients or donors may be legal and appropriate, such as where travel of a related donor and recipient pair is from a country without transplant services to a country with transplant services.

This definition was reviewed in further consultation. First, the suggestion was not to include trafficking in the definition. Then, it was decided to use the one in the Istanbul Declaration.

CONCLUSIONS

At the end of the meeting the Editorial Group had approved 24 definitions and proposed some others.

Dr Luc Noël, Coordinator of the Clinical Procedures Unit in WHO, thanked all the participants for their input to the meeting.

In the light of the discussions, he noted the need to modify some of the questions included in the Questionnaire. It was agreed that explanations would be added as well as the Glossary once agreed, with the purpose of getting harmonized responses. Some adaptations would be necessary in both, the Glossary and the questionnaire, to avoid discrepancies between them.

Dr Noël stressed that the work had to continue in order to reach consensus for all definitions proposed. He said that the next step would be the circulation of the working document among participants and to receive their feedback.

Participants had the opportunity to review all the definitions even if they were already agreed during the meeting or whether the definitions were proposed. Some of them were modified because other factors were contemplated.

After this consultation process, the attached document has been elaborated to include all definitions, the source of each of them and comments if they are appropriate.



Data Harmonization on Transplantation Activities and Outcomes: Editorial Group for a Global Glossary

7-8 June 2007, Geneva HQ, Switzerland (Room M.605)

List of Participants

Dr Inés ÁLVAREZ SALDÍAS

Director

Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos

Hospital de Clinicas, Avenida Italia s/n

Montevideo, Uruguay

E-mail: indt@hc.edu.uy or alvaines@hc.edu.uy;

Dr Mohamed Salah BEN AMMAR

Representative, Centre national pour la promotion de la

Transplantation d'Organes - Tunisie (CNPTO)

Sidi Daoud 2046, Tunisia

E-mail: MS.benammar@rns.tn

Dr Liliana BISIGNIANO

Director, Technique Scientific Direction

INCUCAI

Ramsay 2250

Buenos Aires 1428, Argentina

e-mail: lilianabisigniano@fibertel.com.ar / direccioncientificotecnica@incucaigov.ar

Dr Jeremy CHAPMAN

Director, Acute Interventional Medicine

Westmead Hospital

Westmead, NSW 2145, Australia

E-mail: Jeremy_chapman@wsahs.nsw.gov.au

Ms Lisa COSCIA

Transplant Registry Research Coordinator

Thomas Jefferson University

1025 Walnut Street

605 College Building

Philadelphia, PA 19107

E-mail: lcoscia@aol.com

Dr Razeen DAVIDS

Division of Nephrology and Department of Medicine

Stellenbosch University and Tygerberg Hospital

P.O. Box 19063

Tygerberg 7505, South Africa

E-mail: mrd@sun.ac.za

Dr Francis DELMONICO

Director of Medical Affairs
The Transplantation Society
Massachusetts General Hospital
Dept of Surgery
White Bldg 505
55 Fruit Street
Boston, MA 02114-2696, USA
E-mail: francis_delmonico@neob.org

(Member of WHO Expert
Advisory Panel on Transplantation)

Dr Visist DHITAVAT

Director, Organ Donation Centre
Thai Red Cross Society
5th Floor, Terd Prakiat Building
Henry Dunant Rd, Pathumwan
Bangkok 10330, Thailand
E-mail: dhitavat@yahoo.com

Dr Beatriz DOMINGUEZ-GIL

MD, PhD
Organización Nacional de Trasplantes
C/ Sinesio Delgado 6, Pabellón 3
28029 Madrid, Spain
Email: bdominguez@msc.es

Mr Peter FELDMAN

GAT Registry Program
64 Rodeo Drive
Thornhill, Ontario L4J 4Y3, Canada
E-mail: peter.feldman@petrah.com

Dr John GILL

University of British Columbia - St Paul
Providence 6A - 1081 Burrard Street
Vancouver, BC V6Z 1Y6, Canada
E-mail: jgill@providencehealth.bc.ca

Dr Jongwon HA

Department of Surgery
Seoul National University College of Medicine
Seoul National University Hospital
28 Yongon-dong, Chongno-gu
Seoul 110-744, Republic of Korea
E-mail: jwhamd@snu.ac.kr

Ms HAN Joung-Hee

Korean Network for Organ Sharing (KONOS)
Division of Organ Transplant Coordination
National Medical Center
18-79, Ulgiro 6-ga, Gung-gu
Seoul 100-799, Republic of Korea
E-mail: organ-network@hanmail.net / organ-network@mohw.go.kr

Dr Ahmad Adel HASSAN

Professor of Nephrology and Renal Transplantation
Arab Society of Nephrology
Misr 2000 Center
9 Okba Street
Dokki, Giza, Egypt
E-mail: ahmadadel_hassan@yahoo.com

Prof. HE Xiaoshun

Organ Transplantation Centre
The First Affiliated Hospital of Zhongshan University
58 Zhongshan er Road
Guangzhou, People's Republic of China
E-mail: gdtrc@163.com

Ms JIAO Yahui

Programme Officer
Department of Medical Administration
Ministry of Health
No. 1 Nanlu, Xizhimenwai
Beijing 100044, People's Republic of China
E-mail: jiao_yahui@hotmail.com

Dr Bertram KASISKE

Hennepin Country Medical Center
Department of Medicine
701 Park Avenue
Minneapolis, MN 55415, USA
E-mail: kasis001@umn.edu

Dr Nguyen Ngoc KHANG

Senior Medical Officer for Transplantation
Health Policy and Systems Development
Ministry of Health
138A Giang Vo Street
Hanoi, Viet Nam
E-mail: ngngkhang@yahoo.com

Dr Enrique MARTÍNEZ GUTIÉRREZ

Director del Registro Nacional de Trasplantes
Centro Nacional de Trasplantes (CENATRA)
Carretera Picacho Ajusco No. 154 6° piso
Colonia Jardines en la Montaña
014210 DF, Delegación Talpan, Mexico
E-mail: enrique.martinez@salud.gob.mx

Unable to attend:

Dr Rafael MATESANZ ACEDOS

Coordinador Nacional de Trasplantes
Organización Nacional de Trasplantes
C/ Sinesio Delgado 6-8
Pabellon 3
28029 Madrid, Spain
E-mail: rafmatesanz@yahoo.es / rmatesanz@msc.es

(Member of WHO Expert
Advisory Panel on Transplantation)

Dr Robert MERION

Professor of Surgery
University of Michigan Health System
2926B Taubman Center
Box 0331
Ann Arbor, MI 48109-0331, USA
E-mail: merionb@umich.edu

Unable to attend:

Dr Philippe MOREL

University Hospital of Geneva
Chef du Département de Chirurgie
Rue Micheli-du-Crest 24
CH-1211 Geneva 14, Switzerland
E-mail: Philippe.Morel@hcuge.ch

Mr Kevin O'CONNOR

New England Organ Bank
One Gateway Center
Newton, MA 02458, USA
E-mail: kocon@neob.org

Dr Graeme RUSS

The Australia and New Zealand Dialysis and Transplant Registry (ANZDATA)
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South, Adelaide 5011
Australia
E-mail: gruss@anzdata.org.au / Graeme.Russ@nwahs.sa.gov.au

Dr Naoshi SHINOZAKI

Assistant Professor
Department of Ophthalmology
Ichikawa General Hospital
Tokyo Dental College
(Executive Director, Cornea Center and Eye Bank)
Sugano 5-11-13
Ichikawa City 272-8513, Japan
E-mail: naoshi@eyebank.or.jp

Mr Mariano SORATTI

Jefe del Departamento de Informática del INCUCAI
Ramsay 2250,
Ciudad Autonoma de Buenos Aires, C.P. 1428
Argentina
E-mail: presidencia@incucaigov.ar / informatica@incucaigov.ar

Dr Yves VAN RENTERGHEM

University Hospital
Department of Nephrology
Herestraat 49
Leuven, Belgium
E-mail: yves.vanrenterghem@uz.kuleuven.ac.be

WHO Secretariat

Ms Mar CARMONA (Secretary of the Meeting)

World Health Organization
Technical Officer, Clinical Procedures
Essential Health Technologies
Health Technology and Pharmaceuticals
Avenue Appia 20
CH-1211 Geneva 27, Switzerland
E-mail: carmonam@who.int

Dr Steffen GROTH

World Health Organization
Director, Essential Health Technologies
Health Technology and Pharmaceuticals
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
E-mail: groths@who.int

Mrs Christine FAIVRE-PIERRET

World Health Organization
Clinical Procedures
Essential Health Technologies
Health Technology and Pharmaceuticals
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
E-mail: faivrepierretc@who.int

Dr Luc NOËL

World Health Organization
Coordinator, Clinical Procedures
Essential Health Technologies
Health Technology and Pharmaceuticals
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
E-mail: noell@who.int