World Health Organization

First Advisory Meeting for the SONG project

(Standardization of Organ Nomenclature Globally) in collaboration with the ICCBBA

Geneva, 4-5 May 2011

Report

This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization.

The Clinical Procedures team is grateful to the Government of Spain for its support of WHO's activities in the area of cell, tissue and organ transplantation, and to the International Council for the Commonalities in Blood Banking Automation (ICCBBA), an NGO in working relations with WHO, which contributed in the funding and the organization of this meeting.

EXECUTIVE SUMMARY

The number of available organs for transplantation is far lower than the number of people who await them. In attempts to expand transplant opportunity for patients in need, organs are increasingly shared and transported across national borders.

Matching a specific organ to a specific recipient is essential for good outcomes. Transplantation of incompatible ABO blood groups, virally infected, or graft size mismatched organs can result in serious adverse consequences or even death of the recipient of the organ. It is unfortunate that errors in organ identification and allocation have occurred to the detriment of those receiving the organs. In other areas of public safety and quality, acceptance of international standards for nomenclature has led to a clearer and more consistent presentation of information resulting in an improvement in practice and outcomes.

Current organ/donor identification and nomenclature do not consistently characterize the contents of "what is in the box" when an organ arrives for transplantation. The safety of the process of matching an organ with the intended recipient would be enhanced if critical information were to be expressed using an internationally agreed standard nomenclature. Labeling should give reliable and consistent information regarding the source, graft, preservation method, quality, and identifiable risks and should support accurate disposition records.

Standardization of nomenclature for organ transplant products is needed to improve traceability, vigilance, surveillance and activity reporting. Agreeing on a standard nomenclature will also set the basis for the future introduction of a coding system to support electronic data capture. Such developments will help to eliminate human transcription errors and improve data accuracy.

WHO in collaboration with the International Council for Commonality in Blood Banking Automation (ICCBBA), organized the First Expert Meeting for the Standardization of Organ Nomenclature Globally (SONG) project, with the objective of providing a framework to describe organ transplants.

The nomenclature development process was carried out in three steps:

- Creating high level categories of organ, independently of donation / donor characteristics, relevant for transplantation.
- Analysis of relevant characteristics for transplantation purpose, identifying what is relevant for each organ category.
- Organizing all information by type, i.e. creating a structure for 'what is in the box'.

The three components developed are contained in the annex of this report.

This initial framework is proposed to stimulate a discussion within the donation/transplantation community, regarding the essential information that will optimize stewardship of organs donated for transplantation.

It is anticipated that there will be modifications to this proposal in the light of feedback to this report, and further discussion within the SONG Project Team. Comments are welcomed and should be addressed to Dr Luc Noël at the World Health Organization (noell@who.int).

OPENING SESSION

Dr Luc Noël, WHO Coordinator, Clinical Procedures, welcomed participants to the first meeting of the Standardization of Organ Nomenclature Globally (SONG) project.

Dr Delawir Kahn, Professor and Head of the Department of Surgery at Groote Schuur Hospital in Observatory, South Africa, was elected Chair of the meeting and Pat Distler, Technical Director of the (ICCBBA) agreed to be the Rapporteur.

INTRODUCTION and BACKGROUND

Luc Noël started by setting the scene in organ transplantation, providing data from the Global Observatory on Donation and Transplantation (GODT) to show evidence of the practices performed around the world and to present the baseline for the WHO strategy in the field. The gap between the number of organs available for transplantation and the need for organs is increasing because of the progress of health systems in many countries, the ageing of the population and the increasing incidence of non-communicable diseases which has decreased the number of available donors. This gap has led to unethical practices such as commercial transplantation, trafficking and transplant tourism. These entail safety risks for recipients and live donors exposed to sub-standard practices, in addition to contravening basic human rights.

WHO, in collaboration with all stakeholders, has developed a Plan of Work in transplantation that can be summarized by three action areas: policy and ethics; oversight, quality and safety; and access and use.

The WHA63.22 Resolution endorsed the Guiding Principles on Human Cell, Tissue and Organ Transplantation, a set of 11 principles to guide on ethical and legal frameworks on the process of donation and transplantation. These are available on the WHO website at http://www.who.int/transplantation/en

The SONG project comes from a mandate of the World Health Assembly resolution WHA63.22 on Human Organ and Tissue Transplantation that urges Member States to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation; and encourages the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation.

As a response to the shortage in organs and to avoid unethical practices, the Third Global Consultation on Organ Donation and Transplantation held in Madrid in March 2010 developed the concept of striving towards self-sufficiency which includes maximizing donations from deceased persons. Trust in the system is a necessary prerequisite to achieve the best support by the public for organ donation and transplantation as a community resource. The public needs to be educated that donation is a civic gesture, a civic responsibility; it must be part of the school curricula simultaneously with health education and the prevention of diseases that lead to end-stage organ failure. There is a requirement for authorities to ensure credibility and trust through mechanisms ensuring transparency of all aspects of the donation and transplantation system, including activities and outcomes.

Traceability systems are required to ensure the safety of health products of human origin. As stated in World Health Assembly resolution WHA63.22, internationally standardized coding systems would increase the reliability of traceability systems.

Reliable traceability relies on transparency, availability of documentation and international standardization in view of the increasing cross boundary circulation of health products of human origin, including organs. Sub-regional allocation systems such as Eurotransplant, and multinational agreement to ensure timely transplantation such as for livers in an emergency, are routinely resulting in organs crossing national boundaries and therefore being exchanged between national organ donation and transplantation systems. Assistance schemes enabling citizens from less advanced countries to have access to living related donor kidneys abroad create another source of cross border activity. Unethical practices involving the international sale of organ transplantation services, that take advantage of the easy supply of organs from deceased or living unrelated donors in some areas, are universally condemned but they are thriving because of the inability of approved domestic donation and transplantation programmes to meet needs. Such transplant tourism undermines the development of domestic self-sufficiency and should be combated. An internationally agreed basis for coding transplanted organs and their systematic registration would allow an unprecedented level of transparency on the origin and movement of organs. Japan has insisted, in different consultations, on enabling identification of organ transplantation, increasing transparency and the need for an international standard for coding of transplanted organs.

The role of traceability in the safety of health products of human origin (HPOHO) is crucial. Indeed, diseases can be transmitted from donors to recipients and can involve multiple recipients of HPOHO from the same donor. Transmissible diseases may also involve unusual or emerging agents with potential public health threat.

Traceability is therefore the necessary complement to the pillars of safety of HPOHO. These pillars include:

1. Donor selection
2. Testing
3. Pathogens removal/inactivation
4. Justified clinical use
5. Appropriate procedure
6. Quality management

Coding of transplant products supports easy and automated documentation of steps in the process. A systematic display of the nature of the product and its characteristics simplifies checks and increases reliability of communication. Machine readable codes can also be used to automate transcriptions and checks including the practice of “electronic cross match.”

Therefore, standardization of denomination and nomenclature is the basis for a systematic approach useful in the control of ethical and safety risks.

A standardized approach to the identification of transplants and their characteristics can be of help at three levels:

1. Operations for documentation and controls
2. Assessment and oversight whether for reporting or for vigilance and surveillance
3. Research where data management and quality of identification are also a pre-requisite

At the three levels, reliability of transplant identification and related information is essential, whether for professionals involved in the process or for health authorities and regulators .

HPOHO can be defined as encompassing all components of the human body that are donated for therapeutic purpose. The boundaries of concerns related to HPOHO are not

well defined but clearly they include such issues as ethical risks in procurement and safety risks with transmissible diseases.

ICCBBA is participating in this project because of its enormous experience in nomenclature, coding and labeling for blood, cells and tissues. ICCBBA manages ISBT 128 to meet the needs of interoperability among blood transfusion facilities where it is operationally necessary to have coding systems. ISBT 128 is the only comprehensive coding solution adapted to such HPOHOs as blood, cells and tissues, and it is in use in several countries and in all regions of the world. Almost 4000 facilities are registered with ICCBBA and produce about four million products. ISBT 128 is recognized by major scientific and professional societies in the field of cellular therapy as necessary to the international circulation of products required to meet HLA compatibility requirements.

ICCBBA and WHO have developed a common plan of work in line with World Health Assembly resolution WHA63.22 to provide guidance for Member States on "suitable and traceable coding systems".

Discussion:

- Expected outcome of the meeting:

- The meeting should address the following questions: Why? What do we need? How? and When?

- The meeting should identify and reflect needs.

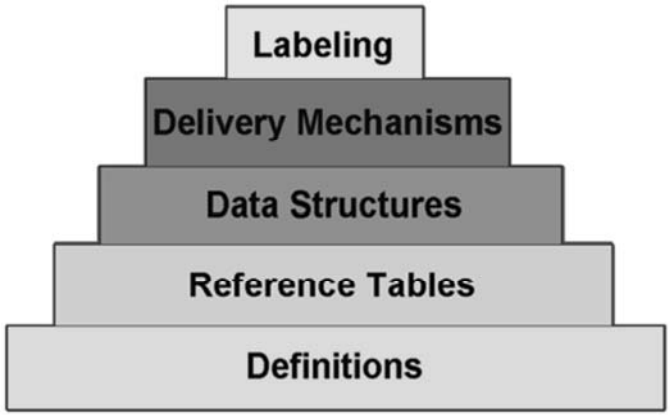
- It is not intended to go beyond the description of the product and its relevant characteristics.

- We need to have one common language instead of several. The nomenclature developed by the group will become the WHO nomenclature. Taking the advantage of the ICCBBA's experience on nomenclature for tissues and cells, it is possible to follow a similar approach for organs.

- Standardized coding based on a globally agreed WHO nomenclature can simplify traceability and could build the foundation of a system to prevent organ trafficking, improve transparency and encourage quality and safety.

Paul Ashford, Executive Director of ICCBBA, presented the "Basis for a global standardized nomenclature system" and the process for developing it.

The information management hierarchy is summarized by the figure below:



- The foundation of the hierarchy is agreed nomenclature (standard terms and definitions), which will be the focus of the group's work. They should be built and managed by international consensus to ensure common understanding and to avoid duplication and ambiguity.
- Reference tables describe products using the agreed nomenclature and provide computer codes for these products.
- Data structures provide the context for communicating the encoded information within and between computerized systems.
- Delivery mechanisms include bar codes, radio frequency tags and computer-to-computer interfaces used to deliver electronically readable information. They are independent of underlying elements of the hierarchy.
- Labeling of products requires defining the information that must be present in both eye readable and electronically readable formats.

Paul Ashford pointed out that it is possible to standardize at different levels of the hierarchy, but to standardize at any one level, all levels below must also be standardized, which means that it is possible to have standardized nomenclature without having a single standardized coding system.

A second approach would be to standardize coding and delivery systems in addition to nomenclature. This would allow facilities to read each other's labels. The actual labels could be different in size, shape and text, but the electronically readable information would be consistent.

Full standardization, including standardized labels, is very hard to achieve because of different regulations and languages in countries. It is not possible to standardize coding if there is not standardized nomenclature.

The process for achieving consensus in nomenclature used by ICCBBA was also described. The recently completed eye bank nomenclature was given as an example. In acknowledgement of the importance of health authorities in the provision and oversight of donation and transplantation services, ICCBBA engages all stakeholders, including health authorities, in the development of its standards. Participants/observers in ICCBBA Technical Advisory Groups include operators, regulators, ministries of health, professional bodies, accreditation bodies, and industry.

Key point:

Following the pyramid graphic, **definitions** can be organized in **reference tables** that associate them with codes (abbreviations designed for efficient computerized communication). The codes can be utilized in **data structures** for use in a variety of electronic **delivery mechanisms**.

OBJECTIVES

Luc Noël indicated that the objective of the meeting was to review the current situation and the possible added value of a standardized nomenclature for organ transplants. The group was then invited to discuss the components of a system to describe organ transplants which would be the basis of a draft document of nomenclature.

This document will be refined through electronic consultation and submitted to an open global consultation system until general agreement allows it to be considered as an internationally standardized WHO nomenclature for organ transplants.

EXPECTED OUTCOMES AND SCOPE

The group spent time defining the scope of the project and the expected outcomes. The output of the group is to be a WHO nomenclature for organs for the purpose of transplantation. It was agreed that nomenclature intended for research or educational use should be included when relevant to transplantation. The nomenclature would be presented in a WHO document created in collaboration with ICCBBA, with ICCBBA participating in the on-going maintenance of the document.

The scope of the project is:

- To provide Members States with the basis for a consistent coding system which includes definitions and perhaps reference tables for solid organ transplants.
- Limited to nomenclature intended for use in donation and transplantation. During the process, the expected nomenclature should standardize the description of the content of the organ box allowing, for instance, reallocation when the intended recipient is not ready for transplantation. The expected nomenclature will be valuable for the clarity of vigilance and surveillance reports as well as for activity reporting. It is understood that the nomenclature attached to coded donation specific information will include an identifier for the transplant that will be registered and used during follow-up. This identifier will be a registration number for the transplant.
- The nomenclature will not go beyond the transplant product. The level of detail of definitions will be determined by the group.

The following issues were considered to be outside the scope of this work group:

- Nomenclature for tissue
- Standardization of terminology describing complications
- Intervention and follow-up processes
- Collection of data, such as how many times a type of transplant had been done
- Standardized labeling

Discussion:

- WHO would like to provide Member States with a consistent nomenclature system with a common reference table. The group should work at this level. Labeling is higher up on the hierarchy and not part of the scope of this meeting except as one of the major uses of a standardized HPOHO nomenclature.

- A label was described as being a type of passport that allows it to go between facilities and countries carrying information essential for identification and traceability. An electronic medical record might be carried by the patient in the future which would contain the information captured from the label. Once the doctor had the information about the transplanted organ from the electronic record, he could request additional information from the facility that performed the transplant.

- ICCBBA has the resources for maintaining the nomenclature. The system will only work with a full global consensus and this meeting group was the core of the global representation to maintain consistency between different regional needs and values.

- Scientific and professional societies have an important role and influence at a national level. Additionally, national health authorities have the responsibility for what is happening in the transplantation field in their countries. Part of WHO's work is to encourage and improve communication between national health authorities and scientific and professional societies. The intention of this process is to involve scientific and professional societies together with the national health authorities.

- Standardized nomenclature can be used in a number of ways and not all require the same level of detail. For example, it can be used for activity reporting at national level which is basic and requires less detail than for operational processes or for the monitoring of outcomes.

MEETING SESSIONS

Round table to share perceptions based on participants' experience, and discussion:

Dr Czerwinski, POLTRANSPLANT, explained that they are working on introducing a system of physical labeling in Poland. They are interested in means of transferring information.

Dr Gupta, Ministry of Health & Family Welfare, India, encouraged the group to identify levels of information that needed to be collected: the bare minimum, the desirable and the optional levels. As regards the coding, it exists for diseases but not for organs. Unique Identification Number (UID) is being given to all nationals which will inter alia identify the live or cadaveric donors and recipients of organs, tissues and cells.

Dr Wang, China Liver Transplant Registry, requested clarification of the purpose of the nomenclature to be developed. That is, whether it was for the allocation of organs or for a registry. Their experience with the liver registry showed that it is very difficult to reach consensus for definitions. There is a need for a task force comprising different organizations to define the scope of variables. In fact there are different layers; for example, minimum requirements versus extensive research.

Dr Noël indicated that it was desirable to have countries using WHO nomenclature to progress towards global harmonization, but recognized change could not be instantaneous. Registries may have existing terminology that could be used. This effort should not be an exercise in creating an entirely new terminology, but should begin by collecting commonalities.

As part of the initial discussion, **Dr Pruett,** Division of Transplantation, University of Minnesota, questioned whether the purpose of the group was to establish nomenclature for traceability or outcomes. He pointed out that outcome information has greater complexity.

The response was that at this stage we should focus on traceability and the description of the organ donation.

While more than one coding system may exist, there is a need for such coding systems to be interoperable through a common nomenclature. The solution should be part of global standards or global guidelines to facilitate communication of information about transplantation for safety, proper management, and proper assessment of outcomes. Essentially, it should provide what is necessary to carry out the health authority's assessment.

Dr Torres, Instituto Nacional Central Unico Coordinador de Ablacion e Implante (lNCUCAI), Argentina, stated that one global coding system was essential because of the international nature of transplant. He mentioned the experience of the bilateral agreement with Uruguay to exchange organs and to perform lung transplants in Argentina since Uruguay does not have the programme. Donors and recipients are from Uruguay. They have the same standards of quality and nomenclature.

Dr Mahillo, Organización Nacional de Trasplantes (ONT), Spain, stated that it was very important to have global nomenclature and coding system to share information and data. She took the example of the Global Observatory on Donation and Transplantation of ONT and WHO. Currently there are countries providing the total figures for livers transplants, but the number of partial liver transplants or splits is unknown. The same applies for lung transplants where it is not possible to know if they are unipulmonar or bipulmonar transplants. Common definitions and nomenclature will contribute towards collecting and exchanging the information more exhaustively.

Beatriz Mahillo explained that Spain has its own database to gather and analyse activity data that uses simple numerical codes, not specific codes. This database does not have the aim of improving the exchange information between regions or countries. In case of exchanges with other countries, all the donor information is sent along with the organ. Traceability can be ensured through a relational model. The post transplant registries are shared with the European Union registries, e.g. the hepatic registry, or with international

registries, like the International Society for Heart and Lung Transplantation registry. She pointed out that the group should consider the different registries that are in place in various countries, and know the codes and definitions used.

She noted that countries from the European Union, as part of the Directive Transposition, will probably have to work on common nomenclature systems and codification to improve communication between European countries in the next two years. The EU has definitions for organs, but not at a detailed level.

Dr Noël pointed out that this progress of the EU in determining common coding gives this project a level of urgency if global compatibility is desired.

Dr Pruett, Division of Transplantation, University of Minnesota, Minneapolis, US, advocated keeping the nomenclature at a simple level stating it could be expanded later; it would be wise to focus on the basics, but structure it in a way that leaves space for additional layers.

Dr Kahn said that neither registries nor allocation systems have been developed yet in South Africa, however they have a good law to control transplantation.

Dr Dhitavat, Thai Red Cross Organ Donation Centre, Thailand, agreed with the goal of a common nomenclature. In Thailand there is a consensus to report to authorities even if there is no organ transplant legislation. A standardized form exists to report information about transplants. Deceased donor records are maintained; however, there is no registry of living donor transplantation.

Dr Ha, Seoul National University Hospital, Republic of Korea, stated that nomenclature devised by the group should be confined only to organ transplants. There is a disparity on terminology used in different regions. It is essential to standardize nomenclature first.

Key points:

- The full string of information associated with transplantation contains items that will not be addressed by the group. The group will be concerned only about the description of the donated organ.
- The pathway of this process will be: i) the outline with basic components (descriptive information, based on existing definitions) will be circulated to a larger group, ii) fields will be adapted according to existing registries or systems, iii) further consultation to be agreed.
- The outcome should combine precision with simplicity as much as possible.

Terminology Discussion

It was agreed that two types of information are required on the donation labeling: donation specific information and the description of the organ.

Donation specific information is information pertinent to donation event. It comprises a donation identification number linked to a unique donor identifier, as well as characteristics/qualifiers, such as immunogenetics, infectious diseases status or ischemia time, that are associated with the donation or donor.

Organ description is the structured categorization of the organ providing information on type of organ, type of graft, quality of graft, preservation medium and consent information.

Discussion:

- The size for kidneys should be indicated.
- Is it a characteristic of the organ that it was donated by a living related or unrelated donor? For some participants this depends on the recipient and does not belong to the product's characteristics. However, the organ donation is directed to a given recipient and this information should appear with the transplant description in order to be accepted by the transplant team. Moreover, a genetically related transplant may have benefits in terms of compatibilities and lower immunosuppression regimen, while an unrelated donor could be motivated by money and hide risk factors for transmissible infections.
- Should the system rely on information available on a distant data management system and avoid reproducing it on the label/documentation of the organ? The infectious marker status is an attribute of the organ but some participants pointed out that this information belongs to the donor file which in some systems is accessible on the Organ Procurement Organization (OPO) data management system for surgical teams. This was seen as a refinement of advanced systems, not precluding the fact that key information for the optimal use of the product should be identified and available in paper format, if only for backup in contingency plans. Another aspect to take into account is the standardization at international level where information has to be shared between independent systems. It is to be noted that in this context coding helps to overcome the language barriers as the same code is translated in each language.
- There was an agreement that the organ description should provide the necessary information for the transplantation team to make the decision to accept and transplant. Therefore all information relevant to the quality of the organ must be

available with the organ including the status for key transmissible diseases. The objective should be to describe what is “in the box”, reflecting and standardizing the key information on the organ currently required by national systems to travel in the container with the organ.

- The donor's age is also a characteristic of the organ impacting on its allocation in some systems.

Specific Comments for Characteristics and Qualifiers:

• Graft quality - Binary response Yes/No. It was decided to make two flags to indicate abnormal function and abnormal anatomy. The flags will say that further information must accompany the organ. However there are different opinions about this. Some participants said that we go too far if we define everything and others said that we have to.

- Examples of abnormal function would include biopsy that shows sclerosis, proteinuria.

- Examples of abnormal anatomy would include damaged artery that needs repair, tumor that has been repaired, stripped capsule; damaged vessels, or anatomical variations.

- Machine perfusion- Binary response Yes/No. If Yes, additional information needs to be included. There will be a link to outcome characteristics of the perfusion.
- The different ischemia time should be addressed because this has a high impact on the quality of the organ. Times should be defined and standardized.

The way forward and conclusions

- The endpoint of this work will be the WHO "Organ Nomenclature", with a minimal set of required information associated with organs for transplantation.

A draft document in the annex, explores the list of qualifiers and a synthetic consolidation of all organs to become the basis of a global nomenclature. It will serve as the working document to continue the consultation process.

- Next step will be to define the terms. ICCBBA will work on putting together the terms and definitions based on the group’s discussions. This information will be shared with the group. The use of existing definitions is encouraged.

- The group will continue working on the document, through conference calls, e-mail, etc. More individuals, with different expertise, will be invited to be part of the group and contribute to the nomenclature as well. Once it is agreed, there will be an endorsement of standards.

- The final document is expected by next year. It will thereafter be updated whenever necessary.

- It was suggested that the consultation process should officially involve Member States of WHO. This is not excluded but premature at this early stage as would be a publication. A text should introduce the initiative on the WHO web site.

The draft nomenclature attached provides the initial model for the information required on the graft label. Further definitions will be required, and some additional information may be identified following further discussion. Dr Noël thanked all participants on behalf of WHO, in particular the Chairman and Rapporteurs.

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