



**World Health  
Organization**

**Second Global Consultation on Regulatory Requirements  
for Human Cells and Tissues for Transplantation:  
Towards Global Harmonization through  
Graduated Standards**

**WHO Geneva, 7-9 June 2006**

**Report**



## **Introductory Note from the Secretariat**

This publication reports on the deliberations and outcomes of the Preparatory Workshop for the Second Global Consultation on Regulatory Requirements for Human Cells and Tissues for Transplantation, held in Geneva from 7 to 9 June 2006. The Geneva meeting represents the second step in WHO involvement in harmonizing global practices in the procurement, processing and transplantation of human cells and tissues, along the requirements of World Health Assembly Resolution WHA57.18 on Human Organ and Tissue Transplantation adopted in May 2004.

This report represents the views of the participants, not necessarily those of WHO. The report is based on a draft prepared by the meeting Rapporteurs, Deirdre Fehily and Martha Wells, who deserve thanks for their dedication and their success at capturing and summarizing complex material with clarity. Deirdre Fehily also played an important role in the preparation of this consultation and her input is gratefully acknowledged, as is the efficient administrative and secretarial support of Christine Faivre-Pierret which was essential in the organization of the meeting. All the participants in the consultation should be thanked for their active participation and their will to achieve consensus. The Secretariat owes special thanks to the Chairman of the meeting, Paul Dubord, for his steady and thoughtful chairmanship.

The report was submitted to all participants for comment. We are grateful to them for their input. Any error or omissions are, of course, our responsibility, not theirs.

Last but not least, it should be emphasized that this meeting was made possible thanks to the Government of Spain's generous support of WHO's transplantation activities.

HTP/EHT/CPR

Luc Noël, Coordinator,



## Executive Summary

This second global consultation aimed to review and take forward the significant outputs of the first meeting in Ottawa in 2004 and to explore and develop further initiatives to improve access, safety and quality in the transplantation of tissues and cells globally. Two WHO Aides-Mémoire were developed following the first consultation and these were discussed and finalized for publication during this meeting. The first is addressed to health authorities and provides guidance on promoting access to cells and tissues for transplantation and on ensuring appropriate oversight and regulation. The second provides details of minimum safety and quality requirements for a shortlist of essential core tissue and cell products. During the first consultation the need for increased transparency in the field was noted and a WHO initiative to publish a Global Knowledge Base on Transplantation on the internet was presented at this meeting and is advancing well. Information and data are being gathered from across the globe to populate the observatory on transplantation that is the result of collaboration between WHO and ONT, the Spanish national agency for transplantation.

Reports on developments around the world demonstrated a common focus on the development of legal frameworks and regulatory structures and systems. A theme emerging from discussions was the need for regulatory and health authorities to consult and collaborate with scientific and professional societies to ensure that the systems of regulation could be successfully implemented. It was recognized that there are great benefits to be derived from scientific and technical societies working together to agree global standards. Speakers described a high degree of international distribution of cell and tissue products, both due to the need for tissue type matching for certain products and due to local shortages. In this context, effective collaboration between regulatory agencies in different countries was also highlighted as a priority. A set of international technical standards for tissue banking, originally published by the International Atomic Energy Agency, will be revised and updated as a joint WHO/IAEA project to promote standardization globally.

As this globalization of cell and tissue transplantation develops, the need for common product names and definitions and for unique product identification becomes essential. Much progress was reported in the standardization of cellular therapy product identification and description using a global standard but equivalent initiatives for tissues were shown to be more complicated and slower. It was considered that WHO could play a significant role in the promotion of common approaches globally to the definition and identification of tissue products and a number of specific actions were agreed to take this forward.

Access is still a major issue, particularly in the Asian and African regions, and the meeting discussed the role of scientific and professional societies in promoting new services. It was considered important that scientific societies in countries where services are well developed should support those in countries where they are still very limited. Some excellent examples of such collaborations were described. It was also clear that collaborative initiatives between neighbouring countries in particular regions resulted in significantly improved access and greater efficiency.

Delegates commented on proposals to update the WHO Guiding Principles on Transplantation which will be revised and reissued in 2007. The new Guiding Principles will be more explicit in their inclusion of tissue and cell transplantation and will address many of the specific ethical and practical issues that arise in this field.

## **Opening Session**

Participants were welcomed to the consultation by Dr Howard Zucker, Assistant-Director General of the Health Technologies and Pharmaceuticals (HTP) cluster of WHO and by Dr Steffen Groth, Director of the Essential Health Technologies (EHT) department within HTP. In his opening remarks, Dr Zucker stressed the importance of the field of cell and issue transplantation globally and noted that these services were growing rapidly and becoming increasingly important aspects of basic healthcare. He illustrated the importance and high profile of this area of healthcare by sharing with the meeting an article published in the New York Times Magazine on 16 April 2006 which highlighted the challenging nature of the ethical, legal and ownership issues in the field of human cells and tissues. Dr Groth referred the participants to the World Health Assembly resolution on transplantation and noted that the topic of this meeting was very much in line with WHO's mandate.

Participants introduced themselves to the meeting. Twenty four countries were represented from all WHO regions. Most participants represented health authorities, including regulators, transplant agencies and policy makers, or scientific and professional societies. The full list of participants is shown at Annex 1.

The proposed Programme of Work was approved by the participants and is shown at Annex 2. Dr Paul Dubord (University of British Columbia) was elected Chairman for the meeting. Ms Martha Wells (US FDA) and Dr Deirdre Fehily (Italian National Transplant Centre) were elected Rapporteurs.

## **WHO Background Session**

### **Overview of WHO Activities and Plans in Transplantation**

Dr Luc Noël, Coordinator of the Clinical Procedures team within EHT, which is responsible for WHO activities in the field of organ, cell and tissue transplantation, outlined the initiatives undertaken and the objectives achieved by WHO since its first meeting on this subject in Madrid in October 2003 (Report available from WHO, ISBN 92 4 159139 0). A major milestone was the adoption of Resolution WHA 57.18 giving a clear mandate to WHO to gather and publish global data on transplantation, to provide technical support to improve access and harmonize standards and to encourage Member States to develop ethical policies in the field.

The publication of the Resolution was followed by the first WHO Global Consultation on the Regulatory Requirements for Human Cells and Tissues for Transplantation which was held in Ottawa from 29 November to 1 December 2004 (Report available from WHO, ISBN 92 4 159329 6). This meeting acknowledged the special status of human cells and tissues for transplantation (HCTT) as a specific class of health product and noted that access to HCTT is very limited in many countries and that international circulation is widespread for certain tissues and cells. It noted that national or regional legislation or regulation is lacking in many geographical areas and that HCTT carry disease transmission risks which must be minimized. The need for national oversight and for quality system approaches in the delivery of these services was greatly stressed. The development of global systems of vigilance and surveillance were considered fundamental to ensuring optimal practice.

Significant technical outputs of the Ottawa meeting comprised two WHO Aides-Mémoire which were in final draft form. The first, 'Access to Safe and Effective Cells and Tissues for Transplantation', is addressed to national health authorities and gives basic guidance on the implementation of systems for oversight and regulation. The second, 'Key Safety Requirements for Essential Minimally Processed Human Cells and Tissues for Transplantation', addressed the technical requirements for a shortlist of essential HCTT and those that are most likely to be distributed across borders. These documents had been developed through global consultation and would be discussed during this consultation with the aim of agreeing final versions for publication.

Dr Noël outlined the differing but complementary roles of regulators and scientific and professional societies (SPS) in ensuring appropriate standards of safety and efficacy. He stressed that the former must put mandatory systems of inspection and licensing in place to ensure the achievement of minimally acceptable standards and the protection of patients in all cases while the latter have a broader role in defining optimal standards and procedures which represent objectives of excellence. The two should always work in collaboration.

A further major output of the Ottawa meeting was an initiative to develop a Global Knowledge Database on Transplantation (GKT) to promote maximum transparency in the field. This initiative had been moved forward with the much appreciated collaboration of the Spanish national transplant organization. The database will have four parts which will provide global information on:

1. Activity and practices
2. Legal frameworks and organizational structures
3. Vigilance threats and responses
4. Xenotransplantation.

Dr Noël outlined future WHO plans in the transplantation field. Priorities included updating the Guiding Principles on Transplantation which were published in 1991 and producing more detailed technical guidance for the collection, processing and storage of HCTT. A series of meetings were scheduled to take forward WHO objectives related to safer and more ethical practice in the field of HCTT transplantation, starting with an international symposium on ethical and policy issues in Zurich in July 2006 which would be co-hosted by the University of Zurich Ethics Centre.

The objectives of the current meeting were presented as follows:

- To continue to develop global tools for the regulatory oversight of HCTT
- To examine issues related to HCTT in international circulation and to propose solutions
- To explore needs and possible methods for developing core global requirements for a coding system for HCTT
- To contribute to the global knowledge base on transplantation
- To collect advice on plans to strengthen access to HCTT vigilance and surveillance information
- To identify further initiatives to improve access to safe and effective cells and tissues for transplantation
- To contribute to the process of updating the WHO Guiding Principles on Transplantation.

In discussion following Dr Noël's introduction, it was noted that there is a European Union funded project entitled the "Property Regulation in European Science, Ethics and Law Project" being run from the University of Birmingham. It is a three-year project which compiles and analyses new approaches in law and ethics to tangible and intangible property in the human genome, information society, plant and animal genomes in relation to biodiversity, sustainable development and food production and human tissue ([www.propeur.bham.ac.uk](http://www.propeur.bham.ac.uk)). It was also noted that the European Association of Tissue Banks published an Ethical Code in 1994 (<http://www.eatb.de/html/standards.htm>).

### **Cells and Tissues in the Global Knowledge Base on Transplantation – GKT Questionnaire for Member States**

Ms Maria del Mar Carmona Sanz updated the meeting on progress with the Global Knowledge Base on Transplantation (GKT). So far, activity has been concentrated on the first part of the GKT, i.e. activities and practices. Work has begun on the establishment of a World Observatory on Transplantation. The aim is to publish available information or data on:

- the numbers of transplants by WHO region (to be published on the WHO website: <http://www.who.int/transplantation/en/>) and by individual country (to be published on the Spanish national transplant organization (ONT) website: [http://www.ont.es/Home?id\\_nodo=124](http://www.ont.es/Home?id_nodo=124))
- information on access to transplants
- information on outcomes in recipients and donors.

The relevant website pages have already been added to the WHO website and data are being inserted as they are received. Sources include national authorities, national organizations, publications and a questionnaire to Member States. It is acknowledged that the data may be incomplete but it is considered important to publish what is available. The questionnaire has been used and will be improved following feedback received. It is structured in two parts, the first on organs and the second on cells and tissues and it requests information on legislation, organizational structures and activity levels. A glossary of definitions is included to assist with questionnaire completion. All participants were asked to send feedback so that the questionnaire can be improved in the future.

In discussion following the presentation, it was stressed by many participants that agreeing common definitions and units for HCTT is fundamental to sharing data internationally in a meaningful way. It was agreed that WHO could lead in this area and should consult related projects such as Eurodonor and Eurocet (both European Union funded projects) where glossaries and definitions have also been developed.

***Key Points:***

***Following Resolution WHA 57.18, the WHO role in the field of HCTT has developed to include fostering:***

- ***transparency of organ, tissue and cell transplantation activities through the GKT***
- ***harmonization of quality and safety standards through the publication of guidance documents***

- *promotion of access to CTTX services through the establishment of networks that could facilitate exchange of information and products*

## **Round Table and Updates on Developments Related to HCTT in Member States**

Brief reports were provided by the delegates summarizing the current status of tissue and cell banking and transplantation in their countries and highlighting significant developments since the Ottawa meeting in 2004.

### **Brazil**

Dr Renato Spindel and Dr José Antonio de Faria Vilaça reported that cornea and bone transplantation have significantly increased in the past year, there was a slight increase for heart valves and bone marrow and a decline for organs. There are 24 ocular, one heart valve and seven cord blood banks in Brazil. Regulations are in place for oversight of transplantation. The national health surveillance agency is working to train inspectors and develop guidance for inspectors as well as develop their system for adverse reaction reporting.

### **Canada**

Dr Alberto Estrada described the new regulatory framework for cells, tissues and organs being implemented in Canada in two phases. Phase one is nearing completion with the implementation of regulations anticipated for the autumn of 2006. Phase two will involve the implementation of inspections, adverse reaction and error and accident reporting.

### **China**

Dr Zhang Xiaodong described the current status of organ transplantation in mainland China. He noted kidney, liver, spleen and bone marrow transplantations have been performed since 1993. He also noted good survival rates for kidney transplants and a waiting list of over a million patients with 120,000 new cases of chronic renal failure registered each year. The contribution of living organ donations is increasing steadily (from <5% to >30%) although on mainland China only a spouse can donate a kidney. China is in the process of enacting a comprehensive legal framework including the definition of brain death. In the meantime, an interim organ transplantation management regulation becomes effective in July of 2006.

### **Colombia**

A national network for donation and transplantation has been created and has been functional for the last year. Accreditation of tissue banks is proceeding. Work is progressing on the definition of criteria for the distribution of tissues for transplantation.

### **Cuba**

Dr Lisette Perez Ojeda described Cuba's regulatory structure for the oversight of cells and tissues. Transplantations of bone, cornea, skin, bone marrow, liver, heart and kidney are increasing. The government is currently implementing phase one of their regulatory framework including the establishment of quality assurance procedures for tissue handling, a clinical trials approval procedure to include the experimental basis for clinical trials and a mandatory adverse events reporting network. Phase two will involve developing inspection and licensing facility criteria.

## **Iran**

Dr Hamid Reza Aghayan reported significant increases in the number of heart valve and bone donations in Iran. He also noted increased use of bone and amniotic membrane. The Iranian Tissue Bank opened a new building in 2005 that includes an ICU and an operating room, as well as research laboratories. Future plans include a new clean room, cell culture laboratory and obtaining ISO certification. They also plan to establish a skin bank, a cord blood bank and to promote pancreatic islet cell transplantation.

## **Italy**

Dr Deirdre Fehily summarized developments in Italy which are primarily focussed on achieving compliance with EU Directives on cells and tissues. All tissue banks in Italy have now been inspected by the National Transplant Centre (CNT) team of inspectors and most have been certified. For haematopoietic stem cell centres, CNT is collaborating with the JACIE (Joint Accreditation Committee of ISBT and EBMT) programme of certification with the aim of conducting joint inspections.

## **Austria**

Dr Johann Kurz indicated that there are 24.6 organ donations per million population in Austria. A system of presumed consent is in place. Cells and tissues are considered medicinal products and the facilities are licensed and inspected by the government according to GMP. Stem cell facilities are accredited by JACIE. Donors must consent.

## **Korea**

Mr Young-Joo Kim reported that a human tissue transplantation law has been in effect since January 2005 for bone, tendon, ligament, cartilage, amnion, fascia, skin, cardiac valves and blood vessels. There are 83 approved tissue banks, most of which are hospital banks and only two are processors. Korea also approves 17 importing facilities, most of which are in the USA, that import mostly bone and some tendon and skin. Eighty four percent of tissue from 2,257 donors procured in Korea in 2005 is bone and 4% is cartilage.

## **Thailand**

Dr Wirote Lausoontornsiri noted significant progress with the implementation of a new Thailand FDA regulation within six months. He indicated that more stem cell therapy is being performed in Thailand. Critical issues for future assessment included safety, efficacy and evaluation of methods.

## **Sri Lanka**

Dr Muhammed Cassim described a 1987 law that controls all transplantation. All establishments must be registered. Donor exclusion criteria for medical history and high risk behaviours are in place. He described methods used for sterilization, packaging, transportation and storage of tissues. Future developments include processing and storing of skin for burns and plastic surgery.

## **Slovakia**

Dr Ján Koller explained that transplantation is overseen by a 2004 law. There are two banks for multiple tissues (bone, skin, heart valve, amnion and cornea) in Slovakia and eight stem cell banks. He noted an unmet demand for bone and that unused corneas are exported.

## **Tunisia**

Dr Mylene Ben Hamida reported two new cornea, two heart valve and one skin bank in Tunisia. All banks in Tunisia are accredited by a professional association. She also noted

that over 900 corneal transplantations took place last year, though there is still a large unmet demand. Because of the increased number of banks, she explained that the government needs to provide a sufficient budget for inspections and training.

### **United Kingdom**

Dr George Galea explained that the European Union Tissues and Cells Directive is now incorporated in UK law and transplantation is regulated by the new Human Tissue Authority. The legislation overseeing tissue banking was recently updated. The UK is planning to initiate an adverse event reporting system. The major safety focus concerns vCJD precautionary measures in the assessment of donors.

### **Spain**

Dr Blanca Miranda explained that the national centre of transplantation has overseen cell and tissue transplantation since the late 1980s. This oversight includes a registry and information on outcomes. She noted that there are 17 tissue and seven cord blood banks in Spain.

### **India**

Dr Sunita Saxena explained that "The Transplantation of Human Organ Act" was passed in 1994 and is the basis of oversight for organs. Over 400 organs have been transplanted from 1995 to 2001. There is concern for possible commercialization of kidney transplants. She indicated that eye banking and corneal transplantation is the major activity in India. There are three banks that are being accredited at this time.

### **France**

Dr Bernard Loty explained that a new 2004 law for transplantation controls all step for cells, tissues and organs and now also includes reproductive medicine. There were 220 banks in France in 1994 and now there are 42.

### **United States**

Dr Celia Witten noted that the FDA fully implemented regulations for human cells and tissues on 25 May 2005. Over 2,000 establishments have registered and 250 inspections are planned for this fiscal year. Implementation activities have focused on the training of personnel including inspectors, inspection and enforcement activities including recalls, development of deviation and adverse reaction reporting systems, registration, guidance development and outreach to stakeholders. Following the presentation there was discussion on recent action taken by FDA to facilitate easier entry of haematopoietic stem cells (HSC) through customs at US borders. This was seen as a positive example of a regulator (FDA) working with an HSC professional organization in the interests of better service to patients. Delegates reported on a number of similar examples of collaboration, particularly between regulators and JACIE in the inspection of HSC facilities. Such collaboration was reported for Austria, Spain, Belgium, Italy and France.

### **Commission Directives in the European Union**

Dr Eduardo Fernandez-Zincke discussed Directive 2004/23/EC as setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human cells and tissues. The Directive has been effective for all 25 Member States since April 2006. This Directive addresses inspection and control measures, import/export, registration and reporting. It also addresses traceability/coding system and the EU is planning a meeting to discuss coding. Directive 2006/17/EC, which addresses donation and procurement requirements, selection criteria and laboratory tests

for donors, will come into force in November 2006. The EU is also developing technical requirements for accreditation, processing, traceability and adverse event and reaction reporting. Future initiatives include guidelines on a coding system, inspections and training of inspectors and on the control of imports and exports.

***Key Points:***

- *Activity is increasing everywhere and it appears that national data is more readily available than it was at the time of the last WHO consultation*
- *There is a major focus worldwide on the development of legal frameworks alongside organizational structures for oversight and regulation*

## **Global Minimal Technical Reference for Operations and Oversight**

### **a) Output of the Ottawa meeting**

#### Aide-Mémoire on Key Safety Requirements for Essential Minimally Processed Human Cells and Tissues for Transplantation

([http://www.who.int/transplantation/AM\\_HCTTmin\\_requirements.pdf](http://www.who.int/transplantation/AM_HCTTmin_requirements.pdf))

Dr Deirdre Fehily summarized the process by which this draft aide-mémoire had been developed before and since the Ottawa consultation. With the input of the delegates at Ottawa, the shortlist of products addressed had been refined according to the agreed criteria: i) required for essential basic healthcare, ii) circulated widely internationally, or iii) subject of a commercial market. The original requirements for donor history, testing, procurement and processing had been distilled from a series of selected national and international standards and regulations. These were further refined through a process of consultation globally and with the WHO Expert Committee on Biological Standards. The final version was provided to the delegates and final comments were invited before publication.

There was discussion on the inclusion of autologous cord blood in the shortlist of products covered by the aide-mémoire. It had been included because of the commercial and international nature of the activity. However, many delegates felt that its inclusion could be interpreted as an endorsement of an activity based on little scientific or clinical rationale. It was agreed that the working group on HSC scheduled for the end of the day should address this issue and make recommendations to the meeting.

#### Aide-Mémoire on Access to Safe and Effective Cells and Tissues for Transplantation

Dr Luc Noël presented the final draft of this Aide-Mémoire (see Annex 3) inviting comments from delegates. In general the aide-mémoire was considered to have adequately addressed the major issues of importance to health authorities in the oversight of cell and tissue transplantation. Various suggestions aimed at improving or clarifying the text were accepted and it was agreed that the final version would be published on the WHO website (<http://www.who.int/transplantation/en/>) in a matter of weeks.

***Key Point:***

- *Two WHO aides-mémoire will be published following the meeting providing guidance to health authorities and practitioners on minimum requirements for the promotion, provision and oversight of core essential HCTT activities*

## **b) Tissue Banking**

### The Contribution of the International Atomic Energy Agency (IAEA) to Tissue Banking

Mr Rick Kastens described the organization and work of the IAEA with particular emphasis on its Technical Cooperation Programme. The programme has funding of US\$92 million provided by contributions from 139 Member States. Over 1,000 current projects in the field of radiation focus on research, technical adaptation for national development followed by evaluation and learning. Almost a quarter of disbursements fund projects in human health. In 1998, the Agency was requested to extend its role beyond assisting in the sterilization of human tissue grafts to supporting the development of quality systems in developing tissue banks to meet international standards and the establishment of viable networks for the donation and distribution of sterilized human tissue.

Consequently, from 1995 to 2002, the IAEA ran a technical cooperation tissue banking programme which included 11 national, two regional and two inter-regional projects, costing a total of US\$5 million. All participating banks are active in the implementation of quality systems and three have achieved ISO 9001 certification. During the programme, supported banks in 21 countries provided 76,643 amniotic membrane grafts, 139,261 bone grafts and 68,831 pig skin grafts. International Standards for Tissue Banking and a Code of Practice for the Radiation Sterilization of Tissue Grafts were developed as part of the programme. Inter-regional training centres in Singapore and Buenos Aires will provide continuing leadership to meet the needs of less advanced institutes. The IAEA's role in QA/QC and business planning training will be strengthened and the tissue banking standards will be updated.

Dr Bernard Loty reviewed the IAEA standards, explaining how they had been constructed. They are largely consistent with other international standards in the field.

### Towards Core Global Standards for Tissue Banking to Facilitate Access to Effective Operations and Oversight

Dr Johann Kurz described the role of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) which now has 28 member countries, 18 within the European Union and ten from across the globe. The organization aims to standardize approaches to pharmaceutical inspection and has an Expert Circle which addresses inspection of blood and tissue facilities. This group met in Canada in October 2005 where they focused on issues concerning the inspection of cell and tissue centres. The meeting was attended by 56 participants from 27 countries, including PIC/S applicant and non-member countries.

The Canada meeting concluded that requirements for cell and tissue centres are similar to GMP requirements for pharmaceutical production and also for blood centres but that there are specific differences that need to be addressed. Experience among member countries represented was limited with many just beginning to inspect these centres or inspecting specific activities only. Some of the challenges of inspection in this field were identified: the difficulty of inspection of procurement; the need for risk assessment to achieve the correct balance between patient safety and continuing supply and the difficulties in establishing proof of suitability of facilities for processing. The need for specialized training of inspectors for this field was acknowledged and PIC/S working groups are now developing guidance. It was stressed that harmonization of inspection approaches is important given the international circulation of many of these materials and

that risk assessment will be an essential element of quality systems in the future. Dr Kurz noted that in many countries responsibility for the inspection of cell and tissue establishments has been given to organizations other than the PIC/S competent authority. He also stressed that many tissue and cell donations are used as a source for gene and somatic cell therapies and for tissue engineering, all of which are generally regulated as medicines. In these cases the preparation environment is of essential importance and must meet full GMP requirements.

### The Role of Scientific and Professional Societies in Facilitating Access to Effective Operations and Oversight of Tissue Banking

#### **c) Corneal Banking**

##### Eye Bank Association of America (EBAA)

Dr Paul Dubord described the role of the EBAA in facilitating access to effective operations and the oversight of eye banking. The EBAA was established in 1961 and has a well established quality assurance programme consisting of medical standards, technical procedures, accreditation of eye banks, certification of technicians and continuing education. In 2004, over 46,841 corneas and 4,549 sclera were provided for transplant. Adverse reactions were reported to EBAA in only 0.053% of the transplantations.

##### European Eye Bank Association (EEBA)

Dr Esteve Trias-Adroher explained that the EEBA was established in 1989 and is comprised of individual members from 83 eye banks from 22 European countries. The EEBA holds annual meetings and has developed minimum standards that include donor medical assessments. Technical guidelines and training courses are available to assist banks maintain the highest possible standards for quality and safety.

The EEBA wished to highlight to the meeting that the involvement of scientific and professional societies (SPS) in the development of regulation was essential to its eventual successful implementation. Dr Fernandez-Zincke stressed that the European Commission is very open to collaboration with SPS. Indeed they consider that the essential principles of 'good regulation' are: 1) simplicity, and 2) involving stakeholders.

#### **d) Haematopoietic Stem Cells and Cord Blood**

##### History and Global impact of Foundation for the Accreditation of Cell Therapies (FACT)

Dr Adrian Gee described the history and global impact of FACT which was founded in 1992 and whose mission is to promote quality patient care and quality laboratory performance in the US and Canada. Accreditation of cell therapy establishments based on FACT standards takes approximately 18 months from the time of application. FACT has 255 trained inspectors and 142 haematopoietic cell facilities have been accredited. He noted that the Center for International Blood and Marrow Transplant Research (CIBMTR) has data which demonstrates that FACT accreditation results in better transplant outcomes.

## Joint Accreditation Committee of ISCT and EBMT (JACIE)

Dr Ineke Slaper-Cortenbach explained the role of JACIE in inspection and accreditation of international establishments to enhance quality management of cell therapy facilities. The third version of the JACIE/FACT standards is published and has been used to accredit 23 establishments to date. Over 100 inspectors have been trained. JACIE is also interacting with the European Union in discussions concerning the implementation of EU Directive 2004/23/EC for setting standards for human cells and tissues. JACIE is currently developing core standards for haematopoietic stem cells including donor leukocytes for infusion. JACIE with FACT, EBMT, ISCT, WMDA and NMDP make up the "Alliance for Harmonisation of Cellular Therapy Accreditation" to pursue the harmonization of their respective standards with the objective of creating a single set of quality, safety and professional requirements for all aspects of cellular therapy from donation to transplantation.

## FACT/Netcord standards

Dr Adrian Gee explained that the purpose of developing these standards (published in 2000) is to globally facilitate supply and demand of umbilical cord blood stem cells and harmonize standards. To date 11 banks and five registries have been accredited based on these standards and 45 others have applied for inspection. Inspections usually take two days and involve three or more trained inspectors.

## The Global Role of the World Marrow Donor Association (WMDA)

Dr Machteld Oudshoorn explained that WMDA works to ensure that high quality haematopoietic stem cells are available for patients worldwide and to protect stem cell donors across borders. The organization has five working groups addressing ethics, donor registries, quality assurance, clinical issues and information technology. She noted that the number of unrelated peripheral and cord blood stem cell donations and the number of registries are significantly increasing as are the number of international donations. WMDA provides an anonymous registry for reporting of serious events and adverse effects.

## **Discussion in Working Groups**

Delegates, divided into tissue-specific groups (tissues, corneas and HPC), discussed issues raised during the day, with particular emphasis on what should be done to move towards global harmonization and standardization and how WHO might be able to help.

The tissue group urged WHO to follow up with Member States to ensure that the appropriate people are aware of the WHO aides-mémoire on cells and tissues. However, it was stressed that in many countries the priority is not to implement systems of certification, licensing or accreditation but to improve access to services. The group felt that the WHO is in a position to influence health authorities and to encourage them to act to improve services. It was also felt that WHO could have a role in identifying needs for tissue banking services in a country and could help to identify those organizations or entities that have the capacity to succeed and that should be supported. The identification of best models for specific countries or regions and the provision of 'how to' instructional technical manuals were also considered priorities.

The cornea discussion group noted that there are two levels of standards: baseline standards of the type produced by WHO and more detailed standards provided by SPS. The greatest challenges to the success of the baseline standards was seen to be communication to the relevant people and regular review and update. It was suggested that WHO should publish the cell and tissue aides-mémoire in scientific journals and that relevant SPS should be asked to provide a link from their websites to the aides-mémoire on the WHO site. It was also suggested that a mechanism for regular review and update should be established and that the documents should be structured in such a way that individual sections can be updated independently.

It was noted that the more detailed standards of the various cornea SPS were very similar and that global harmonization would be an achievable goal. The challenges to achieving this would be lack of motivation, funding and international focus in many of the professional societies. It was suggested that WHO could play a role in encouraging and supporting such an initiative and that a co-sponsored task group might be established to take this forward with costs being shared between the relevant SPS.

The HPC group discussed the development of services in Asia where there appears to be a general gap in the provision of services, although unregulated activity with innovative therapies takes place in some countries. It was proposed that WHO organize a regional meeting in the Asian region for Asian health authorities to promote the development of services and their oversight. There is a recognized need to promote bone marrow donor registries in developing countries.

The HPC group discussed the inclusion of autologous cord blood in the minimal safety aide-mémoire and concluded that it should be removed to avoid any suggestion of legitimization. The issue should be referred to the WHO/University of Zurich Ethics meeting for discussion and recommendations. It should be clear that the same standards for quality and safety required for other cells and tissues should also be required for autologous cord blood.

In general discussion, following the working groups' feedback, it was noted that there is a huge imbalance in services access across the world and a need for models of success and 'South-South' collaborations. In discussion following the presentation, it was suggested that the IAEA standards should be developed as a joint initiative with WHO to create a single global set of technical standards for core, essential HCTT banking to complement the more generic aides-mémoire. Such a document would serve as a tool for both regulators and practitioners. Both IAEA and WHO representatives were supportive of this initiative.

***Key Points:***

- ***Harmonization of safety and quality standards is an achievable goal***
- ***SPS play a leading role in the development of international standards and should work together to provide harmonized standards and guidance in their specialist fields***
- ***The establishment of the Alliance for Harmonization of Cellular Therapy Accreditation and the World Union of Tissue Banking Associations are good examples of global working by SPS***
- ***Involvement of SPS in the development of health authority regulation is crucial to achieving effective implementation***

- *The IAEA tissue banking standards will be revised and reissued as a joint IAEA/WHO set of technical standards to define requirements for core and essential HCTT banking activities for use by both regulators and practitioners*
- *WHO aides-mémoire on CTTX should be widely distributed with the support and co-operation of SPS*
- *Access to HPC services in Asia is to be promoted by a WHO meeting there*
- *Autologous cord blood should not be included in the WHO shortlist of essential core products due to insufficient scientific rationale*

## **The US Experience: Constructive Interaction Between Regulators and Scientific and Professional Societies (SPS)**

### From the Standpoint of the American Association of Tissue Banks (AATB)

Mr Scott Brubaker reported that the AATB regularly interacted with FDA regulators and staff from the Centers for Disease Control (CDC) as well as those from state governments and Health Canada. The FDA has non-voting liaison members on the AATB standards committee and regularly participates in AATB meetings. The AATB actively comments on the FDA's regulations and guidances when they are published and has recently developed recommendations regarding the FDA's Good Tissue Practice regulation that has been forwarded to the FDA to consider in developing FDA guidance. Other interactions with regulators include working with CDC as part of an advisory group to improve communications related to detecting infections among allograft donors and recipients. The AATB is also working with other professional associations to establish and maintain harmonized standards for tissues and cellular therapies.

### From the Standpoint of the US Food and Drug Administration (FDA)

Dr Celia Witten explained the legal framework behind the FDA's authority to develop regulations and policy. She noted the FDA's good guidance practice regulations that direct how the FDA develops, issues and uses guidance documents to help interpret regulatory policy. She then mentioned five guidance documents that have been published as the FDA implements the requirements for human cells and tissues. She reiterated the importance of the interactions between the FDA and the AATB described by Mr Brubaker and also mentioned professional association participation in public advisory committee meetings, educational programmes and workshops. Dr Witten noted that the FDA invites representatives of professional associations to participate in the training of FDA inspectors.

#### ***Key Finding:***

- *There is a need for consultation and collaboration between health authorities and SPS to optimize regulatory requirements and enforcement processes with the shared objective of guaranteeing real improvement in safety and quality while maximizing access to essential services*

## **Oversight of HCTT Establishments**

### **Oversight of Cell and Tissue Banks in France**

Dr Fewzi Teskrat discussed the French Government's extent of oversight for cell and tissue establishments which started with a decree in 1999. France has published several good practice documents with recommendations for procurement and manufacture. He noted that the number of tissue banks has significantly decreased (226 in 1994 and currently there are only 44). Establishments must apply to the French Government and go through an intensive authorization process that can take 18 months including an inspection before they can distribute cells or tissues. Inspections are also performed at international establishments importing into France. He detailed the major deficiencies found during inspections (performed every two years) and indicated a strong focus on education and improvement of safety and quality assurance with regard to the corrective action implemented after the inspection. Dr Teskrat noted an interesting international exchange project with the Czech Republic where France is assisting Czech authorities to develop expertise in this field and train Czech inspectors.

### **FDA's Inspection of Cell and Tissue Banks**

Ms Martha Wells explained that the inspection of cell and tissue establishments is required by regulation and the frequency is at the FDA's discretion and that inspections are generally unannounced. These inspections are performed by trained investigators. They may take samples and review and copy records. If practices are not in compliance a list of observations is left with the establishment to correct. The focus of cell and tissue establishment inspection has been the review of records, SOPs, personnel and training, quality programmes, facility issues (such as environmental control, equipment and storage), tracking systems and complaint files. The FDA can order establishments to recall, destroy or retain products and can take possession of and/or destroy violative products. Other more severe actions include ordering the establishment to cease manufacture, prosecution and fines. Establishments that perform any function considered manufacture (from recovery to distribution) must register with the FDA and there are currently over 2,000 registered establishments (that list musculo-skeletal, ocular, skin, haematopoietic stem cells and reproductive tissues). These include foreign establishments that distribute cells or tissues in the US. Last year the FDA inspected 260 establishments and 50 of them received a list of observations. Ms Wells noted that the FDA might consider using third parties (professional associations) for future inspections but not at this time. Examples of such programmes in place are the mammography quality standards inspections performed by the states for the FDA and the use of accredited persons for device manufacturer inspections.

### **The EUSTITE Project**

Dr Deirdre Fehily described an EU-funded project entitled European Union Standards and Training in the Inspection of Tissue Establishments (EUSTITE). The project has partners from ten EU Member States as well as WHO. The project aims are:

1. Standardization of principles and practices in the inspection and accreditation of tissue banks in the European Union by:
  - definition of current best practice
  - formulation of inspection guidelines
  - development of optimal training for inspectors.
2. Development of a model for the reporting and investigating of adverse events and reactions associated with the quality and safety of tissues and cells in the EU.

It is hoped that the project will start in late 2006 and that it will run for three years. There will be a website which will keep stakeholders informed of progress but particular stakeholders such as PIC/S, JACIE and the European Association of Tissue Banks (EATB) will be actively consulted throughout.

In discussion following these presentations, it was highlighted that a number of recent events have clarified the crucial need for regulators to work collaboratively across national and regional borders. For example, at the end of 2005 a New York tissue procurement company had been ordered to cease operations by the FDA and a recall of tissues was instigated following the discovery that donor histories had been altered or invented. Significant quantities of tissues from the donors concerned had been exported to a number of different countries outside the US. The need for efficient and effective collaboration between regulatory agencies in the US and in the countries affected was very clear in this type of situation.

**Key Point:**

- *There is a need for efficient and effective consultation and collaboration between regulatory authorities across national and regional boundaries to ensure that appropriate and rapid action can be taken to minimize risk to patients*

## **Vigilance and Surveillance: Organization and Recent Findings**

### **France**

Dr Sophie Lucas-Samuel described the French regulatory framework addressing biovigilance for organs, tissues and cells. France requires reporting of incidents occurring, from procurement to distribution, of all unexpected and clinical manifestations in a living donor or a recipient patient. The Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSaPS) received 108 reports in 2004 and 155 in 2005. AFSSaPS coordinates the biovigilance local contact network, assesses biovigilance notifications and coordinates national alerts, information and recommendations.

### **US Food and Drug Administration**

Ms Martha Wells provided a summary of the FDA's new adverse reaction reporting requirements and what has been accomplished since implementation on 25 May 2005. The new requirement mandates that manufacturers must investigate any adverse reaction involving a communicable disease related to a cell or tissue that they have made available for distribution. However, they must report to the FDA such adverse reactions that are considered serious. The FDA formed a Tissue Safety Team (TST) to coordinate responses to reports of adverse reactions and to develop procedures to facilitate rapid and comprehensive responses by the FDA. The FDA has published guidance for completing the Medwatch form and an SOP for procedures for handling the reports. To date 234 reports have been filed and the TST has followed up on 70 of them and no connection has been found with transmission of a disease.

## Canada

Dr Alberto Estrada described Health Canada's vigilance and surveillance organization and recent findings. The Canadian Standards Association first published standards for cells, tissues and organs for transplantation in 2003. Based on the standards, Phase 1 of new regulations will be in place in the autumn of 2006. This will include establishment registration, requirements for traceability and the mandatory reporting to Health Canada of certain adverse reactions. The regulations apply to allogeneic minimally manipulated cells, tissues and organs that can be either viable or non-viable. They do not apply to products for autologous use that are more than minimally manipulated or for assisted human reproduction. No date was provided for Phase 2 which would include enhanced surveillance, compliance and enforcement requirements including inspections as well as error and accident reporting. Eighty percent of tissues transplanted in Canada are imported from the US.

## Brazil

Dr Renato Spindel described the activities of Brazil's national health surveillance agency (ANVISA) that was formed in 1999. He reported 843 organ donors and 4,470 tissue donors in 2005. He noted significant increases in bone and corneal transplantations as well as a significant rise in costs. ANVISA is currently taking new regulatory and policy issues to an expert working group with the goal of reducing risk, increasing safety, traceability and look back with the development of a technical regulation. The Government is interested in implementing inspections and in developing biovigilance and reporting requirements.

### **Key Points:**

- *Many countries are in the process of developing systems for vigilance and surveillance*
- *There needs to be a global aspect to vigilance to ensure that risks and events are communicated and acted on appropriately*
- *Tools for inter-communicability between national/regional programmes are required. WHO's GKT will evolve to provide a global source of information on risk*
- *There was recognition of the pioneering value of the participation of WHO in the EUSTITE project and regulatory approaches and systems for vigilance and surveillance generally*

## Coding System for HCTT

### The Spanish System for Coding of HCTT

Dr Blanca Miranda highlighted the important links between coding, traceability and the reporting and monitoring of adverse events and reactions (vigilance). Directive 2004/23/EC requires that certain information be coded: for the donation, a unique identification number and the identification of the tissue establishment and for the final product a product code (basic nomenclator), split number and expiry date.

The Spanish system of traceability and vigilance relies on the national transplant coordinating network which links the national office with regional and hospital offices where transplant coordinators are located. Connection with processing centres is under

development. It goes further than the EU Directives in terms of the cases for which there is mandatory notification. Notification forms have been reviewed to ensure compliance with the directives. The system is linked with the biovigilance system for solid organs.

The coding system, which is under development, involves the application of information at three separate stages: procurement, processing and final destiny. The donation ID is composed of 17 digits which code for the place of donation (country, city, clinical unit) and for the tissue procured (ID number, type of tissue and split number). The processing code provides information on where the tissue was processed (country, city, tissue establishment) and on the tissue graft produced (admission number, process applied, split number and expiry date). The final destiny code provides information on where the tissue was used or discarded (country, city, clinical unit) and on the procedure applied (process, number and date).

Dr Miranda stressed the importance of secure systems for traceability and vigilance by highlighting that in Spain almost 10,000 patients receive grafts of bone, tendon or cornea each year.

### **Code ISBT128 for Cells and Tissues for Transplantation**

Mr Paul Ashford explained that the objective of ISBT 128 is to provide a standard information environment that supports the movement of blood, tissues and cellular products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated. It is intended that the system should meet regulatory requirements for traceability and information retention. The ISBT 128 standard was developed by the International Society for Blood Transfusion (ISBT) in 1994 for blood and blood products and was later enhanced to facilitate its use for tissues and cellular therapy products, beginning in 2000.

The key elements are:

- a globally unique donation identification number
- an international product description list with definitions and codes
- standard data structures for donation numbers, product descriptions and other information such as expiry dates and HLA profiles.

The standard is maintained by a non-profit organization called ICCBBA and by a series of technical advisory groups of experts working in the fields of blood, tissue and cell banking. The costs of maintaining and developing the standard are recovered from users in the form of registration fees and an annual charge based on the number of donation numbers used.

For blood and blood products, the standard is used extensively in Europe and is being rolled out in North America, two provinces in China, Singapore and Macau. There are registered facilities in Asia, South America, Africa and Australia. There has been rapid progress towards agreement on the use of the standard globally for cellular therapy products. A consensus statement agreed by 11 major national and international organizations involved in the provision of cell therapy products confirmed their support for the use of ISBT 128 for haematopoietic stem cell and other cell therapy products and established a co-sponsored International Cell Therapy Coding and Labelling Advisory Group to promote the adoption of the standard around the world. There are now 85 ICCBBA licenced cell therapy facilities in 19 countries in Europe, North America, South America and Asia.

For tissues, there is significant use in the United Kingdom, where NBS Tissue Services has fully implemented the standard for tissue donation identification and final product description, and limited use in other European countries. In the USA, a joint AATB/ICCBA working group is mapping US tissue products to the ISBT 128 database.

### **General Discussion on Coding for HCTT**

It was agreed that there exists an important opportunity for the WHO to make a significant contribution to promoting a globally harmonized approach to the coding of cells and tissues before disparate systems are developed nationally or regionally, particularly for tissues. Following extensive discussion, a number of actions were agreed:

1. All those present at the Geneva meeting will automatically be members of an informal 'WHO HCTT Coding Working Group' ('A committee of the whole').
2. From that group, a sub-group will carry out work in the area, and provide the outputs to the whole group. This sub-group will ideally include at least the following (participation to be confirmed by these individuals):

Paul Ashford (representing ICCBBA)  
Denis Confer (NMDP and the HPC community)  
Scott Brubaker (AATB)  
Marisa Herson (ALABAT)  
Paul Dubord (Canada)  
Chiyong Ahn (Korean FDA)  
Fewsi Teskrat (AFSSaPS)  
Eduardo Fernandez-Zincke (European Commission)  
A representative from FDA  
Hans Kurz (Austrian Ministry of Health and PIC/S)  
Deirdre Fehily (Italian National Transplant Centre)

All members of the large group will be invited to join the sub-group if they wish to participate.

3. All members of the 'Committee of the Whole' will be asked to submit any lists of described HCTT products that they already have or to provide contact details of any groups currently developing lists.
4. A sharepoint will be set up where all documents collected as part of the initiative will be available to the whole committee.
5. The first task of the sub-group will be to construct a preliminary list of product descriptions – using existing lists or lists under development – and to try to merge them into a single list. To begin with, descriptions will be proposed for the basic and essential product list included in the Key Safety Requirements aide-mémoire and on the basis of the product classification approach adopted at the Ottawa meeting.
6. Once a basic list has been constructed it will be mapped to the current definitions provided by the ISBT 128 product description system to explore its suitability for this purpose.

7. The group will maintain a 'watching brief' on the work of the EU Commission's Coding Working Group to ensure that similar principles are followed by both initiatives.
8. The group will monitor the progress of the HPC professional community in its plan to implement ISBT 128 globally for both donation identification and product description.
9. Having carried out the tasks listed above, the group will make recommendations on how WHO can best promote harmonization of HCTT coding globally through core common requirements for coding systems.

**Key Points:**

- *The group recognized that the commitment to one global coding system for cellular therapy products by the relevant SPS at global level is a very positive milestone*
- *There is an indisputable need for globally standardized labelling (coding and description) for tissues. There is an opportunity to work in a harmonized way before individual countries or regions develop disparate systems; WHO could play a leading role in this*
- *An informal 'WHO HCTT Coding Working Group' will be established comprising all those who attended this consultation*
- *A list will be constructed of product descriptions in existence and will be mapped to the essential core shortlist included in the WHO Aide-Mémoire on Minimal Safety and Quality Requirements*
- *The group will monitor progress in the HPC community and with other initiatives, particularly at EU level, and make recommendations for further WHO initiatives in the area*

## **International Circulation of HCTT**

### **Sub-Regional Cross-Boundary Exchanges of HCTT: Iran**

Dr Hamid Reza Aghayan explained that the Iranian Tissue Bank is the largest of only ten heart valve banks in Asia. It provides more than 300 heart valves a year and has been exporting these within the Middle East region since 1999. Although the bank also procures and processes other tissues, exportation is limited to heart valves and these are most in demand in neighbouring countries which do not have heart valve banks and they cannot all be used in Iran. This programme has allowed a single tissue bank working at high standards of safety and quality with stringent donor selection criteria to share these grafts with neighbouring countries ensuring maximum utilization of valves of all sizes. The Iranian bank can provide heart valves at much lower prices than other countries because of lower salary and shipping costs. There are legal limitations which arise from religious fatwas and which allow exportation only to Muslim countries. Dr Aghayan and colleagues aim to promote education and information provision and to convince public and religious opinion that tissue donations should be used to treat any patient who needs them.

## **Sub-Regional Cross-Boundary Exchanges of HCTT: Colombia**

Dr José Navas described the evolution of the bone and tissue bank which is run by the Cosmos and Damien Foundation in Colombia. The bank was established in 1988 with support from the Miami Bone and Tissue Bank and is operated as a private, not-for-profit organization. It is unique in the region in the sense that it procures tissue at four centres in Colombia, processes it in one central location in Bogota and then distributes it to all of Colombia and to seven neighbouring countries (Panama, Costa Rica, Venezuela, Bolivia, Peru, Ecuador and Honduras) on a cost-recovery basis. Since 1991 the bank has procured donations from 1,701 donors, processed 37,767 bone grafts and supplied 54 hospitals. Dr Navas presented the programme as a model for the organization of local and national procurement and distribution with centralized regional processing. This approach has allowed the implementation of high quality system and safety standards, the benefits of which can be shared with other countries in the region.

## **International Circulation of Compatible Haematopoietic Progenitor Cells (HPC)**

Dr Denis Confer presented on behalf of the Alliance for Harmonisation of Cellular Therapy Accreditation. He demonstrated that international circulation of HPC is an inevitable consequence of the need for HLA-matching between donor and recipient. He showed that patients in countries with less well-developed bone marrow donor registries are far more likely to find matching registered donors in countries with well-developed donor registries and genetically mixed populations. Thus countries such as the USA export large numbers of donations while countries such as Mexico import many donations each year; some countries import more than half of their grafts. Rare countries with very homogenous populations and well-developed registries, notably Japan, import and export few donations. Of the 4,842 unrelated collections of peripheral blood stem cells (PBSC) and bone marrow carried out globally in 2005, 39% were exported to another country for transplantation. Of the 1,126 unrelated collections of cord blood transplanted in 2004, 35% were exported to another country for transplantation. Dr Confer estimated that 90% of global activity is reported.

Despite this widespread movement of HPC globally, much progress has been made to gather data on transplant outcomes. In Europe, the European Society for Blood and Marrow Transplantation (EBMT) has data on more than 250,000 transplants and in the US, the Centre for International Blood and Marrow Transplantation has equivalent data on 230,000 transplants.

## **General Discussion on the International Circulation of HCTT**

In discussion following these presentations, it was noted that the international circulation described highlights the need for regulators from different countries and regions to speak to each other. The benefits of SPS working together were also clear and the example of the collaboration between HPC organizations globally was much lauded. Various strategies had been developed to overcome regulatory barriers, for example, US centres provide document and label packs to countries abroad that are collecting HPC to send to the US, thus ensuring that all US requirements for labelling and documentation will be met.

Colombian representatives expressed some frustration that despite the positive work being done in the sharing of bone grafts regionally, there were problems of image and trust resulting from perceptions of 'business' or 'profit' motives. It was agreed that

education was required to ensure transparency. The focus should be on meeting patient needs though the balance between importation and the development of local services has to be considered. Dr Teskrat stressed that programmes of inspection and accreditation give credibility and reduce suspicion. Dr Herson suggested that regional agreement on pricing and allocation criteria would also help to increase confidence in services being offered regionally.

It was noted that the Iranian programme has an excellent history of supporting WHO standards and recommendations for tissue banking. The WHO could work with health authorities in the Eastern Mediterranean Region to promote greater sharing of resources along the lines of the Iranian model.

**Key Point:**

- *Given the existing and increasing extent of international movement of HCTT, regulators globally should liaise closely to ensure that compliance actions, including adverse reaction reporting and follow up are appropriately communicated*

## **Access to and Oversight of HCTT Services – Case Studies**

### **The Cornea Bank of Sri Lanka**

Dr Muhammed Cassim described how the International Eye Bank had been developed in Sri Lanka since its establishment by the pioneer, Dr Hudson Silva, in 1961. Since the eye bank programme began, 28,910 corneas have been provided for transplant in Sri Lanka and 47,288 have been exported to 58 cities in 61 countries, primarily to Asia but also to South Africa and to some European countries. In 1996, a Human Tissue Bank was established which stores other tissues such as bone, tendons and amniotic membrane that are either deep frozen or freeze-dried. This bank also exports surplus tissue to China, India, Japan and other countries in the region. The banks have been visited by experts sent by the IAEA to assist with the development of their quality systems.

As a result of the Buddhist support for donation after death, tissue donation rates are very high and Dr Cassim reported that 81,000 people are currently registered to donate after their death. This explains the continual capacity of the banks to provide surplus tissue grafts to other countries.

### **Cuban Experience**

Dr Lisette Perez Ojeda described the Cuban health system, explaining that all 11 million citizens have equal access to free healthcare regardless of race, sex or religion. Cuba has a long history of cell and tissue transplantation with bone transplants first being performed in 1942. Since then, organ, cornea, skin and HPC transplantation programmes have all been developed. A statement regarding the individual's wish to donate is included on the ID Card but there is a shortage of donors. The national sanitary regulation authority has been empowered by the Ministry of Health to control all aspects of tissue and cell banking including inspections, quality system guidance, pre-market approval and post-market surveillance and import and export.

## General Discussion on Improving Access in Resource-Limited Situations

When asked what the main priorities for support to the tissue banks would be in Sri Lanka Dr Cassim responded that a new facility is being built for the eye bank and that they would benefit from expertise to ensure that the design and quality is fully compliant with international standards. From a quality and safety point of view, the major challenge for the eye bank is the lack of adequate local facilities for donor testing which means that samples have to be sent some distance for testing. This has resulted in corneas being released (though not transplanted) before the test results were available.

Dr Saxena from India reported that the major need there is a statutory body to regulate, inspect and accredit activities. It was stressed that, apart from certain circumstances where marginal donations might be transplanted on the basis of a risk/benefit analysis, all donors should be tested for virology markers and no grafts should be released from a tissue bank until negative test results have been recorded. It was felt that a service such as that being provided by the Sri Lanka Eye Bank in an environment where resources are limited should, nonetheless, achieve the highest international standards of quality and safety, given the scale and geographical breadth of the service. Dr Noël urged the delegates to work with their national health authorities. Any WHO support in these areas would have to follow requests from the national health authorities.

Dr Gee raised the possibility of support to developing services by SPS. He described a very positive collaboration between FACT and the Indian Government which is helping to develop cellular therapy services there. Dr Dubord described a similarly successful collaboration where the Eye Bank Association of India is working actively with US eye banking experts to develop services to a high quality level. Dr Akinsola from Nigeria highlighted the fact that activity and standards are generally developed by SPS before national health authorities introduce regulations. It is therefore essential to support the development of SPS in those countries where access to cell and tissue services is very poor.

### **Key Points:**

- *The establishment and work of scientific and professional societies (SPS) will be an important element in the development of cell and tissue transplantation activity in those countries where access to cells and tissues for transplantation is limited*
- *Such organizations will be well placed to make links with global SPS and with national SPS in countries with well developed services*
- *The WHO role is to support Member States in response to requests from them to develop suitable CTTX services, in particular by facilitating international cooperation*

## Update of WHO Guiding Principles on Human Transplantation

Dr Luc Noël introduced the WHO Guiding Principles on Human Transplantation which were endorsed by the World Health Assembly in 1991 (WHA 44.25). The 1991 Resolution recommended that "Member States take account of the Guiding Principles in the formulation of their own policies on human organ transplantation and that by appropriate means they disseminate the idea of multi-organ donation for human transplantation from deceased persons". The Guiding Principles were built on four fundamental concepts:

1. Preference for deceased over living organ donation
2. Preference for genetically related over unrelated living donors.  
Preconditions in all cases:
  - i. informed consent by a competent person
  - ii. free of undue influence or pressure
3. Non-commercialization
4. Fair distribution of organs

Since 1991, the context has changed considerably. Shortages of donors and difficulties in many countries in identifying potential deceased donors, together with technical advances resulting in greater clinical success with living donors, have resulted in a move towards the promotion or facilitation of living donation in many countries. The total prohibition on commercialization has also become controversial with some arguing that it is paternalistic to refuse payment to a living donor.

WHO now wishes to update the 1991 Guiding Principles, broadening them to overtly address also the donation of cells and tissues and taking account of the changing environment since original publication. A process of global consultation began during 2005 and continues through 2006 at all WHO regional, technical or ethical meetings in the field. The aim is to present revised Guiding Principles to the WHO Executive Board in January 2007 and, with their approval, to present a final draft version to the World Health Assembly in May 2007.

Dr Noël then concentrated on those Guiding Principles which have so far been consistently identified as possibly requiring revision (Principles 3, 4 and 5) and presented a draft text for their revision and for three additional Guiding Principles (Principles 10, 11 and 12). Both the content and the wording of the proposals were debated in full and all comments recorded for submission to the consultation process.

## **Recommendations and Actions**

During the closing session the Rapporteurs presented the following key points arising from the meeting. They were agreed by the delegates.

- All participants agreed to send comments and suggestion for improvement to the Global Knowledge Base on Transplantation Questionnaire within two weeks.
- The lack of a comprehensive legal framework for HCTT in most countries in the Asian regions should be a focus of WHO work. A WHO regional meeting should be organized in the Asian Regions to address the development of HPC donation and transplantation there.
- WHO to collaborate with the IAEA to elaborate a methodology and workplan to achieve the goal of a global 'technical guidance document' for tissues, to include ocular tissues.
- Although there is a global commercial market in the storage of cord blood for family use, and the safety and quality requirements for such activity are equivalent to those outlined in the WHO aide-mémoire, this product should be removed from the shortlist of products covered in the aide-mémoire due to the lack of evidence of its clinical usefulness.

- Issues related to the ethics of commercial banking of autologous cord blood should be referred for review to the WHO/University of Zurich meeting from 17-19 July 2006 on ethical aspects of cell and tissue donation and transplantation.
- It was considered essential that the experience and expertise of SPS are fully utilized in the development of regulations by health authorities and that these organizations can also play a key role in the development of services in countries with limited access.
- It was stressed that SPS globally should work together to provide harmonized standards and guidance in their fields. The establishment of the Alliance for Harmonisation of Cellular Therapy Accreditation and the World Union of Tissue Banking Associations were good examples of global working by SPS.
- Regulators globally should also liaise closely to ensure that adverse reactions and other compliance actions are appropriately communicated.
- There should be effective dissemination of the WHO aides-mémoire and meeting outcomes and systems developed to ensure the regular updating of WHO guidance documents.
- There was recognition of the importance of a WHO link with EUSTITE and regulatory approaches and systems for vigilance and surveillance.
- The group recognized that the commitment to one global coding system for cellular therapy products by the relevant SPS at the global level is a very positive milestone.
- There is a recognized need for standardized labelling (coding and description) for tissues. The meeting considered that there is an opportunity to work in a harmonized way globally before individual countries or regions develop disparate systems and that WHO could play a leading role in this.
- A *WHO HCTT Coding Working Group* will be established to explore the possibilities and to work to develop a core list of product definitions. The group will make recommendations on how WHO can best promote harmonization of HCTT coding globally through core common requirements for coding systems.
- The establishment and work of SPS will be an important element in the development of cell and tissue transplantation activity in those countries where access to cells and tissues for transplantation is limited. Such organizations will be well placed to make links with SPS in countries with well-developed services and to approach their health authorities to urge them to seek WHO support.

## List of Participants

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7-9 June 2006, Geneva HQ, Switzerland (Salle D)

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## Programme of Work

### Wednesday, 27 September 2006

#### Opening Session

- 09:00 Welcome and Introduction by Director EHT/HTP Steffen Groth
- 09:10 Objectives of the meeting Luc Noël
- 09:15 Introduction of Participants
- 09:30 Comments on Programme of Work
- 09:35 Election of Chairpersons

#### WHO Background Session

- 09:40 The follow up to Resolution WHA57.18 from 2004 to 2006 Luc Noël
- 09:50 The Global Knowledge Base on Transplantation  
GKT questionnaire for Member States Mar Carmona
- 10:10 The ONT-WHO Global Observatory of Transplantation Blanca Miranda
- 10:20 General discussion
- 10:30-10:50 Coffee/Tea Break**
- 10:50 Organ trafficking, transplant tourism Luc Noël
- 11:10 General discussion
- 11:20 Human cells and tissues for transplantation Deidre Fehily  
Annette Schultze-Baldes
- 11:40 General discussion

#### Perception of current issues in transplantation, regional and national illustrations

- 11:50 Mohamed Ben Ammar
- 12:05 Jeremy Chapman
- 12:20 Jiye Zhu
- 12:35 Francis Delmonico
- 12:50 Deirdre Fehily

#### **13:05-14:00 Lunch Break**

#### Perception of current issues in transplantation, regional and national illustrations, continued

- 14:00 Tomonori Hasegawa  
Naoshi Shinozaki

14:15 Adewale Akinsola

14:30 Farhat Moazam

14:45 Adib Rizvi

15:00 Paul Dubord

15:15 Blanca Miranda

**15:30-15:50 Coffee/Tea break**

**Perception of current issues in transplantation, regional and national illustrations, continued**

15:50 Carl-Gustav Groth

16:05 Pietro Majno

16:20 Yongyudh Vajjaradul

16:35 Esmeralda Luciulli

16:50 Leonardo de Castro

17:05 General discussion

**18:00 End of session**

**Thursday, 28 September 2006**

**Updating the WHO 1991 Guiding Principles: review and discussion of draft updated text**

**09:00 Introduction to future Guiding Principles on Transplantation**

Luc Noël

**Discussion on working document, concept, preamble**

**Round table discussion**

**10:30-10:50 Coffee/Tea Break**

**Discussion on working document, concept, principle and commentary**

**10:50 Preference for deceased over living organ donors (Guiding Principles 1, 2 and 3)**

Round table discussion introduced by Alex Capron

**12:00 The live donor, related and unrelated, the minor and consent (Guiding Principles 3 and 4)**

Round table discussion introduced by Leonardo de Castro

**13:00-14:00 Lunch Break**

**14:00 Non-commercialization (Guiding Principles 5, 6, 7 and 8)**

Round table discussion introduced by Farhat Moazam

**15:30-15:50** *Coffee/Tea break*

**15:50 Fair distribution of organs** (Guiding Principle 9)

Round table discussion introduced by Dan Wikler

**16:00 Additional technical Guiding Principles**

**Monitoring**

**Transparency**

**Patient safety and quality of care**

Round table discussion

**17:00 General Discussion**

**18:00 End of session**

**Friday, 29 September 2006**

**09:00 Summary of the previous day**

Rapporteurs

**09:15 Global Consultation on Transplantation, March 2007**

Participants and draft programme of work for the March consultation

General Discussion

**10:30-10:50 Coffee/Tea Break**

**10:50 Planning for a Global Forum on Transplantation**

10:50 How to best advance a common global attitude in transplantation

Luc Noël

11:00 Lessons from the Global Collaboration for Blood Safety

Neelam Dhingra

11:15 General Discussion

**11:45 Action points and conclusions**

**12:30 Closure of meeting**

Access to Safe and Effective Cells and Tissues for Transplantation

[http://www.who.int/transplantation/AM\\_HCTT\\_AccessSafety.pdf](http://www.who.int/transplantation/AM_HCTT_AccessSafety.pdf)

Attached