Second Global Consultation on Critical Issues in Human Transplantation: Towards a Common Attitude to Transplantation

Geneva, 28-30 March 2007

Report
Introductory Note from the Secretariat

This consultation was made possible thanks to the Spanish Ministry of Health's generous support of WHO's transplantation activities.

This publication reports on the deliberations and outcomes of the Second Global Consultation on Human Transplantation: Towards a Common Global Attitude to Transplantation, held in Geneva from 28 to 30 March 2007. The consultation was the culmination of the process carried out following 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. 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, Carl Groth, for his steady, thoughtful and vastly experienced chairmanship, and to the two very efficient Rapporteurs, Paul Dubord and Beatriz Dominguez-Gil, who prepared the first draft of this report.

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.

Luc Noël, Coordinator Clinical Procedures
Essential Health Technologies
OPENING SESSION

Welcome and opening remarks
Howard Zucker, Assistant Director-General

“Good morning: Welcome to all and thank you for coming to this important meeting. Today we have 54 participants from 35 countries representing all WHO regions, so we are well placed to make real progress.

This Second Global Consultation on Human Cell, Tissue and Organ Transplantation aims to work towards a common global attitude to transplantation. What we mean by that is that we need to reach agreement on four points:

• that the person, whether recipient or donor, must be our main concern both as a patient and as a human being
• that commercial exploitation of human material will not lead to equitable access to organs
• that organ donation from live donors poses numerous risks which can be avoided by promoting donation from deceased donors
• that quality, safety, efficacy and transparency are of the essence if we are to reap the benefits transplantation can offer as a therapy

The meeting today takes place three and a half years after the first, held in Madrid in October 2003. The last meeting, “Ethics, access and safety in tissue and organ transplantation: Issues of global concern”, led to World Health Assembly Resolution 45.18 in 2004. This Resolution urged Member States to take a number of measures on oversight, transparency and accountability in the procurement, processing and transplantation of human cells, tissues and organs, and to improve the safety, quality and efficacy of human material and transplantation procedures. The Resolution also urged action to protect the poorest and most vulnerable groups from “transplant tourism” and the sale of tissues and organs.

So where are we today? To meet the requirements of the Resolution, WHO has constituted networks with national health authorities, scientific and professional societies and NGOs. Thanks to all these stakeholders working towards a common purpose, transplantation is progressing and gaining momentum. We are seeing some countries taking concrete steps to protect donors and recipients and formulating policies to ensure quality, safety and efficacy. On this point I would like to cite progress made by China and Pakistan, as shown in the laws recently enacted in those countries. But more must be done, and faster.

As a next step, we would like to propose an update of the WHO Guiding Principles devised in 1991, in order to reaffirm the fundamental value of patient safety and to make transplantation live up to its promises everywhere in the world. The future model Guiding Principles should take on board safety and quality requirements to make transplantation a model of clinical practice for recipients and donors alike and a model of accountability so that we can increase public trust. They should also take stock of current realities.
We know that access to transplantation services is the only chance some patients have of surviving and living a quality life. Transplantation is on the increase and is performed everywhere, including in some of the poorest developing nations. Kidney, liver haematopoietic stem cells, cornea and skin transplantations are increasingly in demand and they are seen as proof of high-level tertiary care and of an advanced medical system.

However, the growth in the number of transplantations performed does not match the number of patients waiting for the organ that will save or greatly improve their life. This has led to the development of live donation with inevitable risks to donors.

Non-existent or lax laws on donation and transplantation in some countries have opened the way to exploitation of the human being through coercion to donate organs or payment without proper medical follow up of the donor. Likewise, the vulnerability of the recipient is often exploited. We have seen cases of individuals and companies procuring tissues from deceased donors with little or no regard to quality, efficacy and safety. These people see the risks and outcomes of transplantation only in terms of monetary profit and loss. Transplant tourism epitomizes the dangers of trafficking in human material.

Exploitation of the human body is a very real risk. The gap in supply has led to proposals for markets where organs can be bought and sold. Human material for transplantation, as a new class of health products of human origin, should be a concern for national health authorities of all countries, in particular cells and tissues circulating across boundaries.

As I mentioned earlier, the development of donation from deceased donors has to be kept high on the WHO Member State’s list of priorities. For safety and also for ethical reasons, products for transplantation need to be properly identified. Traceability as a safety measure should be made easy by common coding systems. This is an area where WHO can assist by facilitating harmonization.

As Head of Health Technology and Pharmaceuticals, I must also underline how the cost of immunosuppressive regimes can weigh heavily on organ recipients in the long run. Lack of long-term access to these medicines can annul all the benefits reaped from transplantation.

For all these reasons, the updated Guiding Principles, while preserving the fundamental content of the 1991 version, need to reflect changing realities, as shown by the Global Knowledge base on Transplantation. We expect this week's consultation to pave the way for a common global attitude to transplantation that will be worthy of the challenges before us and adapt to evolving circumstances.

As a final note, I would like to highlight the crucial support we have received from the Government of Spain for our transplantation activities. I extend WHO’s gratitude, once again, to the Minister of Health”.

Geneva
28 March 2007
KEY POINTS:

The meeting aims for agreement on the following:

- the person, donor or recipient, must be of prime concern as a patient and as a human being
- commercial exploitation of cell, tissue and organ (CTO) transplantation must be avoided
- live donation has risks to be avoided by emphasis on deceased donation
- quality, safety, efficacy and transparency are of the essence if we are to reap the benefits that CTO transplantation can offer as a therapy

Objectives of the meeting:

Luc Noël, for Steffen Groth, Director EHT

The objectives of the meeting are based on the need to match the actual realities in transplantation. It was proposed that three documents should be produced for the governing bodies: a report on the status of transplantation; a draft resolution on actions that WHO and the Member States should take; and an update of the WHO Guiding Principles.

The participants introduced themselves and the following officers were elected:
  Chair: Carl Groth
  Rapporteurs: Paul Dubord and Beatriz Dominguez-Gil

KEY POINTS:

Three documents should be developed for the governing bodies as a result of the present meeting:

- a report on the status of transplantation
- a draft resolution on what WHO and Member States should do
- an update of the WHO Guiding Principles on transplantation

BACKGROUND AND UPDATE

WHO in transplantation: a look back and the way forward

Luc Noël

Luc Noël outlined the history of WHO in the field of transplantation from October 2003, when the First Global Consultation on Human Transplantation took place. As a result of this meeting, Resolution WHA 57.18 was taken, emphasizing the need for:

- oversight by health authorities of allogeneic and xenogeneic transplantation
- collection and analysis of data
- update of the Guiding Principles on CTO transplantation
- improvement of access to suitable CTO transplantation
• global harmonization of practices (safety, quality, efficacy and ethics)
• prevention of exploitation of the poor and vulnerable

The Secretariat requested a network of collaboration, examining relevant issues in transplantation through specific consultations. The Global Knowledge base on Transplantation (GKT) was launched in 2006 and based on four components:

1. activities and practices
2. legal framework and organizational structure
3. threats and responses
4. xenotransplantation

A review was provided of past and future activities already developed and to be developed in the context of these four components.

The establishment of a Global Forum on Transplantation (GFT) was proposed, with the aim of working towards a common global attitude on transplantation. The GFT would bring together all stakeholders in transplantation, facilitating an information exchange, analysing the current situation in transplantation worldwide, in particular from the GKT, and identifying issues and potential solutions. It would provide WHO with advice and recommendations and WHO would ensure the broad dissemination of the GFT's findings.

KEY POINTS:

An outline of the history of WHO was given in the field of CTO transplantation from October 2003, when the First Global Consultation on Human Transplantation took place. As a result of this meeting, Resolution WHA 57.18 was taken. The Global Knowledge base on Transplantation (GKT) was launched in 2006 and is based on four components:

1. activities and practices
2. legal framework and organizational structure
3. threats and responses
4. xenotransplantation

Safety and quality in CTO transplantation was seen to be a primary issue

Global situation. The Global Knowledge base on Transplantation (GKT)

Mar Carmona

The rationale for the GKT is based on:

• the lack of accurate data on transplantation activities throughout the world
• the lack of documentation to estimate the extent of ethically unacceptable practices, and the efficacy and safety of transplantation in different conditions and settings
• the lack of a legal framework in some countries

Preliminary data were presented on transplantation activities at a global level and in WHO regions. Data sources were represented by:

1. national authorities
2. national organizations
Specifically data on activities for 98 countries (81.7% of the global population) in 2005 (or 2004 if no figures were available for 2005) were presented. Grouped by WHO regions, the 98 countries were distributed as follows (AFR: 3 countries; AMR: 21 countries; EMR: 12 countries; EUR: 41 countries; SEAR: 8 countries; WPR: 13 countries).

At the global level, estimates for kidney, liver and heart transplantations were 66,000, 21,000 and 6,000, respectively. In kidney transplantation, the ratio of donations from deceased donors (DD) to donations from living donors (LD) varied across the WHO regions (from 4.55 in EURO to 0.05 in EMRO). Detailed information on activities for each WHO region is provided in Figures 1 and 2.

**Figure 1:** Annual global estimates for kidney transplants. Absolute number (per million population). Ktx: Kidney transplants. DD/LD: Deceased donor/living donor ratio.
There appears to be a relationship between the Human Development Index (HDI) and kidney transplantation on the one hand and the DD/LD ratio on the other. For instance, countries with a high HDI are responsible for 60% of kidney transplantations performed and show a DD/LD ratio of 2.2. Countries with a medium HDI are responsible for 38% of the global kidney transplantation activity and their DD/LD ratio is 0.86. Finally, those countries with a low HDI are responsible for 0.1% of kidney transplantation.

Information provided by the World Bone Marrow Association (WBMA) estimates a global activity in unrelated haematopoietic stem cell transplants (HSMT) of 9,500 (3,125 from bone marrow, 4,800 from peripheral blood and 1,575 from cord blood). It was concluded that collection of information on transplantation, although slow, is ongoing. However there is still missing information and some of the data is poor. There is an urgent need to improve the quality of the information by working in close collaboration with the countries and striving for standardization of data.

**KEY POINTS:**

Progress on collection of accurate and reliable information on global donation and transplantation activity is ongoing, but it is a slow process and there is a real need to improve the quality of information obtained.
Global situation. The ONT-WHO Global Observatory on Donation and Transplantation (GODT)

Blanca Miranda

Blanca Miranda gave an overview of the technical basis and content of the ongoing GODT and how it intends to fulfil some of the requests reflected in Resolution WHA 57.18. The GODT provides the opportunity to introduce and collect data on donation and transplantation activities as well as information on organization and legislation frameworks on transplantation across WHO Member States. It also allows the possibility of introducing and collecting information on activities, events, news and documents of international or local relevance, as well as specific information about “how to become a donor” in any of the countries.

The GODT will have public and private access. Public access will not be in place until the approval of national delegates has been given.

Concerns were voiced after this presentation on the technical way the website is to be updated and maintained, issues that are still to be decided. Specifically, access to the website was a concern. Stakeholders will have access to this site for input in the very near future.

Delegates designated by each country will be in charge of reviewing and correcting the data already collected and updating information on the situation in their respective countries.

In general terms, it was concluded that the work performed is impressive and that it will indeed provide the basis for research and improved quality of care, with more accurate, reliable and updated data on transplantation activities.

KEY POINTS:

The Global Observatory on Donation and Transplantation represents the technical means to collect global information on donation and transplantation activities, legislation and organization, information that was requested in Resolution WHA 57.18. Public access to this website, which has already been created, will not be in place until the approval of delegates of the Member States.

Global situation. Mapping transplant tourism

Yosuke Shimazono

An excellent preliminary detailed survey on transplant tourism was provided. Information was collected from articles in journals, transplant tourism websites, registries and reports from health authorities.

Four different modes of international organ trade and trafficking were described, the information presented according to countries of donors and recipients and the country in which transplantation was performed (Figure 3).
**Figure 3:** Modes of international organ trade and organ trafficking, according to the number and type of involvement of countries affected

Transplant tourism is facilitated by third parties: individual brokers, agencies, hospitals or transplant centres, patients’ networks, doctors, embassies or transplant tourism websites on the internet.

Major destinations ('host countries') for 2005/2006 were identified, China and Pakistan having the highest number of transplant tourists per year (1,000-2,000). Major 'client countries' were also identified, Saudi Arabia and Taiwan having the highest number of transplant tourists, 700 and 450 respectively, during 2005. Outprisingly, the number of patients going abroad from some countries far exceeds the number of transplants carried out in those countries.

Negative consequences of transplant tourism affect both the donor and the recipient. Some reports have already described worse than expected patient and graft survival figures for the recipient, as well as a high rate of post-transplant complications.

For kidney 'donors' there is a negative impact on physical, psychological and social health. Also, reports on abuse, fraud and coercion are common. Social repercussions, mainly the distrust of the medical establishment, complete the picture of negative implications of transplant tourism.
KEY POINTS:

- Transplant tourism is facilitated by third parties
- Major destinations and client countries were identified
- Consequences for the recipients, reflected in some reports, were described as providing worse than expected patient and graft survival figures, as well as a high rate of post-transplant complications
- For kidney 'donors' there is a negative impact on health, and reports of abuse, fraud and coercion are common
- Social repercussions, mainly the distrust of the medical establishment, complete the picture of negative implications of transplant tourism

COUNTRY PROGRESS, LEGISLATIVE FRAMEWORK

China
Jiye Zhu

China is a large and populated country with rapid development in the fields of economy, science and technology. In this context, people demand higher health care levels which, taken together with the quick development of medical technology, has led organ transplantation activities to increase rapidly within the country. For instance, in 2005 more than 8,000 kidney transplants, more than 3,000 liver transplants, 134 heart transplants, and even some cases of solid organ combined transplantation, were performed. The results of transplants in terms of survival figures seem good and have been improving in the last year according to registry information.

The Chinese Government was aware of the need for national legislation to regulate transplantation activities. In March 2006 the Chinese Ministry of Health published the “Interim Provisions on the Administration of Clinical Application of Human Organ Transplant Techniques”, containing the following principles:

- only medical facilities and physicians attaining a certified level can perform human organ transplantation
- organ transplantations will be monitored and supervised by the Organ Transplantation Technique Clinical Application and Ethics Committee
- the doctor must follow the principle of informed consent and must have the donor’s written consent
- an adult’s living donor organs must be genetically related to the recipient. No organ should be removed from the body of a living underage person for the purpose of transplantation
- organ trafficking is forbidden
- the human body and its parts cannot be the subject of commercial transactions. The giving or receiving of payment for organs is prohibited
- the allocation of organs must be according to need
- organ quality must be established to prevent the dissemination of disease
• the medical facility should report and register the category, number and result of the organ transplantation within a specific time

This outlined national legislation came into place in March 2007. Currently progress is registered both for living and deceased donors. As far as living donation is concerned, an increase in the number of living donor organ transplantations from a relative has been observed in the last year. In the case of deceased donation, although China is currently developing national brain death legislation, it is already performing brain death donor transplantation. The same donation principles mentioned previously apply to executed criminal donors, namely the need for voluntary consent or a family member's agreement before donation can be carried out.

Finally, although China has made great progress in organ transplantation, two main obstacles need to be addressed:

1. there is a lack of information among the general population regarding the concept of brain death
2. China needs to improve the registration system for organ transplantation. A national donation network will be set up

Pakistan
Adib Rizvi

Pakistan will soon have legislation in place to curb the organ trade. A proposed Ordinance on transplantation is under discussion. The Ordinance has some very positive points which are as follows:

• the Government has recognized the need for a law on the transplantation of human organs and tissues
• it states that transplantation for foreigners will not be permissible
• it makes the provision for registering transplant centres and transplant teams together with maintaining a registry for transplantation

However, some clauses in the Ordinance unexpectedly enable ongoing commercial transplantation. The clause on “living donors” states: “Close blood relative until the second degree”. This means parents, sisters, brothers, half sisters, half brothers, uncles, aunts, first cousins, nephews and nieces, wet mothers or her children. However, there is no method of checking relations through a “wet mother and her children”. “Non-blood relatives” include husband, wife and relatives by marriage (in-laws). There will be no limit of relatives by marriage, but who would check the authenticity of in-laws?

The clause on “donor pool” is unclear. It states that rules shall be framed to establish and regulate the pool of voluntary donors and the registry of potential recipients, this clause being ambiguous not differentiating between voluntary living and deceased donors. It may legalize vendor pools.

The clause on “compensation” states that the amount of compensation payable to a donor shall be recovered from the recipient. It authorizes and promotes kidney vending as being legal – this is commercialism. This will enable abuse and exploitation of the most vulnerable sections of society, e.g. “the poor, bonded labourers and women”.
Another clause refers to an “Evaluation Committee”. In the event of non-availability of a donor and the threat to life of an end stage renal disease patient, the Committee may allow donation by a non-relative, after satisfying itself that donation is voluntary and not for payment. The law limits itself to kidney transplantation only where the option of dialysis is available as a life saving measure for years. There is no mention of other important transplants, i.e. liver, heart, lung, etc., where patients of end stage disease are dying every day and there is no such alternative. This in fact allows the Evaluation Committee powers to decide on unrelated transplant on the pretext of “saving a life”.

Adib Rizvi concludes that the new Ordinance as currently written will not end the illegal trade in organs and that the poorest will continue to be exploited.

Philippines
Leonardo de Castro

In the Philippines there is a 10% limit placed on foreigners who want to be organ recipients. However, in 2006 this limit was only respected by one hospital (not the other transplant centres) and there is strong lobbying for the lifting of this requirement.

Rampant trafficking in human organs is admitted (3,000 people in one slum admitted to selling kidneys). It is known by Department of Health officials that “the donor gets about 50-70,000 pesos and the rest goes to middlemen, sometimes the doctor, sometimes the travel agency, sometimes relatives or friends of the patient”. Some donors claim they were duped and that they were paid the second half of the amount due only when they produced another donor.

Regulated sale through a Department of Health clearing house is carried out (with payment of 300,000 pesos for an organ – 200,000 to the donor and 100,000 for a medical check-up). To regularize this situation, a draft consensus statement has been developed which states:

- human dignity must be respected and should be a paramount principle of organ donation. Individual decisions to donate organs must be respected. The donor must be recognized for this selfless act and priceless gift of life and his welfare must be placed on an equal footing with that of the recipient
- a regulated system for organ donation must be put in place, taking into account the welfare and interests of donors and recipients and the principles of respect for persons, beneficence, non-maleficence and justice

Finally, the stigma of vending organs exists: “one person who had been paid still insisted that he was a ‘donor’ rather than a vendor”.

Russian Federation
Vadim Zelenev

At the present time there are 15,000 people in Russia who need a kidney transplantation. There are also thousands of potential recipients on the waiting list for a heart and liver transplant. Every year, the number of people requiring transplantations increases by 5,000. The majority of them die before they have a chance to be operated on.
In Russia one cannot buy an organ or obtain it without getting on a waiting list. Organs themselves are free of charge, regardless of where they come from, whereas the operation and the follow up have a price, and quite a high one. An exception can be made only in the case of a personal donation, that is when a relative or a friend gives an organ specifically to the patient concerned.

If the donation is impersonal, the organs go to one of the centres of the national transplantation programme and are distributed among specialized medical institutions, according to the number of the people on the waiting list. The organs removed from cadavers are allocated in the same way. Obviously, in all cases a thorough examination is carried out of the donor’s tissue and organs and those of the recipient to establish their compatibility with regard to immune factors.

Of paramount importance is the increasing need for cell, tissue and organ donation. This need and the way in which the public can participate should be communicated clearly to the public, even to school children.

Islamic Republic of Iran
Bagher Larijani

We must emphasize general guidelines, but the interpretation of guidelines may be different. We must accept diversity among countries, according to their cultures and health services.

The Iranian model of Organ Donation from Living Unrelated Donors is related to its situation, with 25,000 patients with end stage renal disease in 2006 and over 40,000 patients expected for the year 2021. Iran supports a call to promote deceased donation, but it is thought that this approach is not enough. The following actions on Living Unrelated Donation have therefore been implemented:

- an effort to eliminate the 'broker'
- members of transplantation teams have no role in the identification of potential donors
- rewarded gifting is reimbursed via the Charity Foundation of Special Diseases, which is an NGO
- transplantation from Iranian donors to non-Iranian is banned
- transplantation from immigrant donors to Iranians is likewise banned
- prior to transplantation, the donor is examined by the nephrologist and finally assessed by the transplant team

As a result of this programme, Iran has eliminated its renal transplant waiting list.

India
Vineet Chawdhry

The Government of India passed the Transplantation of Human Organs Act in 1994. The Act prohibits commercial transactions in human organs and facilitates transplantation where the donor and the recipients are near relatives. For unrelated cases, authorization committees are set up to ensure that there is no commercial motivation for the donation of the organs. For registration of hospitals undertaking transplantation, appropriate committees have been set up in all the states of the country.
A change in the legislation has been sought for simplifying procedures. A committee was set up in 2004 and a report submitted in 2005. Recommendations include a series of changes in procedures for donations in unrelated cases. "Swap donations are being promoted. Benefits have been introduced for living donors. These include a comprehensive health care scheme to be developed by the Government; a lifelong free renal/liver check up and follow-up care in the hospital where the transplantation has taken place; the establishment of a customized life insurance policy to be funded by the recipient; a system of honour donors; compensation for loss of income; and travel concessions on Indian railways. It has also been recommended that a programme to promote deceased organ donation should be set up.

The Government of India has decided to have a national consultation on all the recommendations of the committee. This exercise has been entrusted to the Rajiv Gandhi Foundation (an NGO). Comments on the recommendations of the committee have been already been invited. A final view will be taken after the conclusion of the consultation process.

The Government of India has now decided to launch a National Programme for Organ Donation and Transplantation with effect from 2007.

Japan

Masaharu Tanto / Naoshi Shinozaki

Japan has a very restrictive law on brain death (requires a donor card for deceased donors and allows a family veto) which leads to very few deceased donors. In fact, only 50 transplants over the last decade have taken place since the law was enacted in 1997. This country is trying to increase deceased donation as a whole by applying the Spanish model. Japan is aware that public promotion has a very transient effect on deceased donation, although there is great support among the public (60% support donation).

The percentage of need is underestimated by physicians. Therefore, the need to educate physician and health care providers is great. Japan’s approach is based on the importance of education and training. Currently, Japan is attempting to improve data collection on patients receiving transplants abroad.

Japan explained that it had legislation that prohibited organ trafficking of its citizens, both in Japan and in other countries. It suggested that reimbursement of loss of income of the donor should be carefully discussed.

**KEY POINTS:**

A general very positive session on the progress made by different countries on the steps to an appropriate legal framework on transplantation, constructed on the basis of WHO Guiding Principles.

Some Member States are responding to the need to take measures to protect the poorest from the transplant trade and transplant tourism. To be highlighted is the excellent progress made by China, with new national legislation on Human Organ Transplantation coming into place very recently.
Pakistan has a proposed Ordinance on transplantation. Although positive in the sense of providing the need for legislation on human organ transplantation, it contains several clauses that may not prevent ongoing commercial transplantation.

INCREASING DONATION AND ACCESS

United States of America

James Burdick

James Burdick described the Organ Donation and Transplantation Breakthrough Collaboratives, used by the Federal Government to increase organ donation. The number of organ donors has progressively increased since the first Donation Collaborative. Collaboratives on donation and transplantation are “committed to saving or enhancing thousands of lives a year by spreading known best practices to the nation’s largest hospitals, to achieve organ donation rates of 75% or higher in these hospitals.” Collaboratives represent an intensive, full-court-press to facilitate breakthrough transformations in the performance of organizations, based on what already works. They are designed to define, document and disseminate good ideas, accelerate improvement, achieve results and build clinical leaders of change.

The final result should be an increase in the percentage of eligible deceased donors from whom organs are obtained and an increased number of recipients who benefit from organs from each donor. For instance, Collaboratives started at 6,000 donors/year and three organs/donor, which means 18,000 recipients/year. The United States has already moved to 8,000 donors/year, which means 24,000 recipients/year and aims for 9,000 donors/year and 4 organs/donor, which will mean 36,000 recipients/year in the near future.

Finishing his presentation, James Burdick formulated the following questions:

- What is the role/promise of organ transplantation now?
- What will it be in 10 years? 20 years?
- How will more health benefits from transplantation be achieved?
- How will physical and social harm from inappropriate transplant activities be minimized?
- How uniform or diverse should practices and laws in different areas be?

Spain

Blanca Miranda

Even with the highest donation rates described in Spain, the needs for kidney transplantation are not fulfilled: 100/million population kidney transplants would be needed to cover incidence and prevalent cases of end stage renal disease. Several approaches were discussed to increase access to transplantation: optimizing brain death donors, special programmes (split and domino transplantation), living donors and non-heart beating donors (NHBD). With regard to this last type of donor, figures are not quantitatively impressive but improving in Spain and with good results, providing the basis of understanding that other alternatives for increasing access to transplantation are real.
Lack of detection of the potential donor and high refusals to donate seem to be two important limitations when optimizing deceased donation. With regard to refusals to donate, not only promotion, but also training of health care professionals is an important component to the success of the programme. In fact, a survey performed among the general population in Spain on three different occasions (1993, 1999 and 2006) revealed a lack of change in the attitude of the population towards donation. Despite this, refusals to donate progressively decreased during this period (from 27.6% to 15.2%). This observation would be compatible with a better approach to the family as a probable result of intensive and specific training of professionals approaching the families.

Saudi Arabia

**Faisal Shaheen**

Particularly in recent years, many patients in Saudi Arabia have been going abroad to get a kidney transplant from unrelated living donors. These transplants are associated with higher infectious and post-surgical complications and negative economic effects on families and relatives. Due to the organ shortage, expanding the donor pool through the use of living unrelated donors (non-commercial) could be considered an approach.

The Kingdom of Saudi Arabia proposes a model for Living Unrelated Kidney Donation based on the idea of altruism: "without setting rules with regard to unrelated living donation, the donors could be exploited by the mediators". Measures proposed include:

- directed/non-directed donation in a voluntary act
- national supervision by a governmental centre such as SCOT
- a special committee to evaluate the donors (medical, non-medical and ethical experts)
- respect of donor rights and medical fitness
- rewarded gifting by government (life-long insurance, grants, etc.)
- recipients' rights to be protected (no harassment by the donors for extra benefits)

Reward to donors will include:

- long-term medical insurance
- reimbursement for absence from work due to organ donation
- governmental society service medal
- discount on Saudi Airlines

Incentives (reward gifting) remain a matter of continuous controversy. In the Kingdom of Saudi Arabia, the new act for living unrelated organ donation will compensate rich and poor alike for the absence from work by the Government whether the donor is a Government employee or not and whether the donor is genetically related or unrelated to the recipient.

Faisal Shaheen believes that the Kingdom of Saudi Arabia’s project of unrelated living donation is timely with regard to decreasing commercial transplantation in other countries and to controlling the practice of transplantation within Saudi Arabia.

Tunisia

**Mohamed Ben Ammar**
The number of end stage renal disease (ESRD) patients on renal replacement therapy (RRT) in Tunisia reached 6,700 in 2006 and is expected to reach 8,700 patients in the next five years. Ninety per cent of the RRT patients are on haemodialysis, less than 2.5% on peritoneal dialysis. Six hundred and fifty kidney transplantations have been performed since 1986. In Tunisia the total cost of RRT is covered by the Government, being totally free of charge to the patient.

With regard to organ transplantation, 90% of the source is represented by related living donors, with a scarce representation of deceased donors. The demand for human cell, tissue and organ transplantation has very significantly increased in recent years but the number of transplants performed has not increased.

In this context two main issues for the healthcare system are the shortage of organs and the high cost of RRT, bearing in mind that kidney transplantation represents the cheapest way of treating ESRD and is the therapy that provides the best quality of life.

In the field of transplantation Tunisia may be considered a developing country with:
- legislation on transplantation
- a fully developed and well implemented legal framework
- brain death certification
- a well defined process from deceased donors (DD) and from related living donors (RLD)
- authorization or licensing of institutions and programmes
- principles for safety and efficacy
- coordination of services and allocation of human material
- full traceability
- ethical requirements: absence of commerce, confidentiality, non-related living donors (NRLD) and publicity are prohibited, transparency and equity has to be 100%

With regard to deceased donation, Tunisia is dealing with the two systems for consent to donate, presumed and explicit consent, with high rates of refusals (approximately 85%). A study revealed that the majority of families did not provide a reason for their negative decision. These observations outline the fact that education and promotion should be considered of prime importance to increase deceased donation.

The main goals for the next ten years in Tunisia are to reach self-sufficiency in organ transplantation, to reduce living related donation and to increase deceased donation. To cope with these goals the proposed approach may be summarized as follows:
- to perform research
- to create an obligated system for the ICUs to declare all cases of brain death
- to implement the concept of “Department of Transplantation”
- to provide special support for medical departments for each donor identification and transplantation event
- to encourage teams to be on call
- to force the centres with RRT to prepare their patients for kidney transplantation
- to improve communication through the media, increasing public awareness of the value of organ donation and encouraging people to get on the ID card
- to develop education programmes, carefully designed and consistently implemented, to be included in the school curriculum
Mongolia
Noosgoi Oyuntsetse

Mongolia is the country with the lowest density population (2.7 million people in a country three times the size of France).

Several steps have been taken in the field of end stage renal failure. A haemodialysis unit has been made functional with 12 machines at the present moment. CAPD has started. A transplant team with 14 trained personnel has been set up. Eight related living kidney transplants have been performed. Immunosuppression is based on induction with Campath, low dose monotherapy and no steroids in the maintenance period. This immunosuppression represents 30-40% of “normal published costs”.

Problems encountered include a high incidence of hepatitis A, B and C. One death in the context of an acute liver failure was due to reactivation of hepatitis six months after an uneventful kidney transplant.

Two positive steps have been taken:
• codification and legal verification of brain death
• implementation of WHO Guiding Principles for related living donors and recipients

Mali
Mahamane Maïga

After much deliberation, Dr Maïga chose the following title for his presentation: "Poverty should not be a handicap for kidney transplantation accessibility". Some African countries have demonstrated that they can achieve successful kidney transplantation for an individual at a cost of US$10,000. This is actually the case in Sudan. He continued by demonstrating that kidney transplantation can be implemented successfully in a poor and low income country like Mali.

The Nephrology Department was founded in Mali in 1981 at the University Hospital “Point G” in Bamako. In 1997 the first and only haemodialysis unit was opened. Finally, the first living donor kidney transplantation was performed in 1998 in collaboration with the urology department at “Pitie Salpetrie” in Paris. Since this first kidney transplant 19 more kidney transplants from living related donors have been performed. This low number is explained by the cost: each kidney transplant costs US$100,000 which has to be covered by the individuals involved.

In an environment of absolute poverty (with critically high infant and maternal mortality), kidney transplantation is also considered a cost-effective procedure. Issues that justify a kidney transplant programme in Mali may be summarized as follows:
• reduces renal disease rehabilitation costs (dialysis)
• reintroduces young and able patients with end stage renal disease into productive life
• promotes medical education at university and hospital levels
• improves health practices and quality in different departments of the university hospital

To develop a kidney transplant programme some issues should be covered: political support, law reinforcement, drug supplies, renal biopsy specific to RT, specialized manpower, improved laboratory conditions (HLA histocompatibility, CMV detection), specific RT laboratory panels,
postgraduate training for different specialists implicated in the RT team, financial support and structural development of the transplantation unit.

As a whole, transplant programmes must be developed with a commitment from the government to provide medical and specialized training and to improve the overall quality of care.

KEY POINTS:

Donor and organ shortage remain a universal problem that it is being addressed in countries with different approaches according to local needs, facilities and level of social and economic development.

CELL AND TISSUE SERVICES

Safe and effective cell and tissue transplantation services

Deirdre Fehily

Deirdre Fehily underlined some key features of cell and tissue transplantation. As far as the scale of activities is concerned, although information on tissue activity is difficult to provide, some examples of the large scale of activity may be given: 1.5 million tissue grafts distributed by AATB-accredited tissue banks each year, >200,000 tissue grafts in Germany, 46,000 corneas distributed by Sri Lanka Eye Bank over 30 years.

Dr Fehily pointed out that cell and tissue transplantation is usually life-enhancing rather than life-saving, except in the case of haematopoietic stem cell transplantation.

The ability to store and process cells and tissues for transplantation has certain benefits: the opportunity to reduce risks, to maximize utilization and to store items until needed, therefore with little wastage. However, the ability to store also generates some risks: contamination and cross-contamination, poor quality due to poor preservation and mislabelling and mix-ups with loss of traceability.

One donor can give cells and tissues to many recipients (up to 40 tissue units from one single donor).

With this type of transplantation there is global circulation of cells and tissue, for example 40% of bone marrow donations are transplanted in a country other than the one where they were donated. The AATB 2002 survey on 59 banks describes tissues from 23,000 donors distributed to the US and to 39 other countries.

Commercialisation is represented by the existence of for-profit tissue banks with multinational activity, the processing of tissues by patented methods with licensing to banks, the for-profit and not-for-profit brokers facilitating international tissue distribution and the selling of cell storage services for family use: an example of exploitation is represented by great medical promises derived from the use of stem cells from cord blood.
Keeping in mind the characteristics of human cell, tissue and organ transplantation, the need for appropriate regulation is based on the risk related to the donor and the procedure.

WHO has developed Global Consultations focused on Human Cells and Tissues for Transplantation. Key outputs from the second global consultation are:
- two Aides-Mémoire improved by minor amendments
- a common focus on the development of legal frameworks and regulatory structures and systems
- the need for close collaboration between regulators and scientific and professional societies
- the need for scientific and professional societies to work together across the globe
- the need for regulators to collaborate across the globe
- IAEA technical standards to be revised and reissued as a joint initiative with WHO
- WHO Coding Working Group established

Ethical issues in cell and tissue donation and transplantation

Annette Schulz-Baldes

A summary was given on the International Symposium on Ethical and Policy Issues of Human Cell and Tissue Transplantation held in Zurich in July 2006. The discussions of this symposium showed that there was consensus on some issues; that there were open questions that concern cell, tissue and organ transplantation; and also open questions that concern cell and tissue transplantation.

With regard to the agreements, consensus and open questions resulting from the symposium, the following points were raised:
1. The global dimension of human cell and tissue transplantation:
   a. There was consensus on the need for common global requirements also from an ethical perspective.
   b. An open question remained unanswered on how international circulation of HC/HT products affects equitable access to these services and to equity in donation.
2. Consent to donate:
   a. A consensus was reached on the fact that consent for human cell and tissue removal is mandatory and that limitations to withdrawal of consent should be disclosed during the consent discussion.
   b. Open questions remained unanswered on the type of consent to apply (informed versus presumed), the role of the family in obtaining consent and the amount of information to be provided in the donation discussion.
3. Unpaid donation:
   a. There was consensus that HCT transplantation should be unpaid, financial disincentives for donation should be removed and for-profit organizations should not be involved in donation interviews or procurement.
   b. The open questions were: are there “ethical incentives” for donation? And who owns the human body?
4. Stewardship:
   a. The public/not-for profit and private/for-profit structure of HC/HT processing should not automatically imply a moral judgment.
   b. HC/HT establishments act as stewards of a gift.
c. The intention of donation as expressed in the consent discussion should be respected
d. The open questions which remained unanswered were: What are the limits of
determining future use? How should surpluses or profits be managed?

5. Quality and safety management:
   a. Quality and safety management are key to any HC/HT transplantation activity.
   b. Quality and safety management should be comprised of long-term follow up of living
      HC donors and HC/HT transplant recipients.
   c. The traceability of organs and HC/HT should be coordinated.

6. Fair distribution:
   a. The goal of HC/HT services is equitable access.
   b. Transparent allocation criteria are necessary.
   c. Patient needs should be the primary consideration.
   d. What are the correct allocation and prioritization rules?
   e. How does profit making affect the distribution?
   f. How does international circulation of HC/HT products affect equitable access?

7. Recipient consent:
   a. No HC/HT should be transplanted without informed consent.
   b. How much information should be provided during informed consent?
   c. Does consent justify any intervention?

From key safety requirements to harmonization

Paul Dubord

Of primary concern to regulators, stakeholders and, most importantly, the public is the safety and
quality of cell, tissue and organ (CTO) transplantation. To promote these goals, a comprehensive
regulatory framework is required that sets basic medical standards for CTOs, appropriate
regulations and a surveillance system are necessary to ensure ongoing quality improvement.

Crosscutting medical standards cover base line practices that are comprehensive, dynamic and
respond to current scientific knowledge. The process must be transparent with all stakeholders
involved in a background of equality and of development consensus. The Canadian model for
regulation of CTO transplantation demonstrates these characteristics. A cost benefit analysis has
demonstrated at least three to five times the return or benefit for an established comprehensive
regulatory framework.

A critical component of any comprehensive quality safety system is traceability for all transplant
events, for example, the universal coding system.

International harmonization and standardized coding

Naoshi Shinozaki

Organ sharing, tourism and international tissue sharing not only exist but they are increasingly
frequent activities that provide the basis for the need for a standard coding system. This system
should fulfil the following characteristics.

1. It should cover cell, tissue and organ activity.
2. It should deal with new technology.
3. It should be universal.
4. Data storage, maintenance and response to referrals are primarily the responsibility of donating institutes or governments.
5. Donor and recipient privacy should be protected, avoiding donor and recipient identification by an external observer.

In this context of global concern, a strong recommendation to WHO is made: WHO should lead global traceability by producing an “International Shared Coding System” for organs, tissues and cells.

KEY POINTS:

Cell and tissue transplantation have key features to be outlined: large scale activity, mainly life-enhancing, not life-saving, ability to store and process, global circulation and commercialisation. Quality and safety are key issues of human cell and tissue transplantation since risks are real. Surveillance should be put in place based on traceability (maintaining confidentiality) and codification, two critical prior steps.

A strong recommendation was made to WHO to lead global traceability by producing an “International Shared Coding System” for organs, tissues and cells.

ADVOCACY FOR THE PUBLIC AND FOR POLICY MAKERS

World Transplant Games

Maurice Slapak

The World Transplant Games (WTG) had 73 countries represented in 2005 (WHO includes 93 countries with transplant units.)

The two purposes of the WTG are:

1. To increase organ donation:
   WTG has had an impact on the mass media and this has turned into a positive impact in transplantation activity. Figures provided show that the number of transplants performed have increased when compared to the same period in the preceding year to the one in which the WTG took place (in Kuwait, kidney transplantation increased by 71% and deceased kidney transplantation by 450%, comparing the year 2000 with the year 2001, WTG having been held in Kuwait in February 2001). The lesson learned is therefore that “What people think and know is what matters”.

2. To aid full physical, psychological and social rehabilitation, Maurice Slapak concludes that “The bringing together of organ transplant recipients from some 73 countries in fair and healthy sporting activity plays a significant role in achieving WHO’s Guiding Principles”.


Roberto Tanus
A summary of the Second World Day for Organ Donation and Transplantation was presented. Conclusions derived from this day establish the need to promote the commitment from national and international authorities; regional integration; the development of new lines of action; and the participation and interest of citizens.

The Kuwait Statement and the World Day of Organ Donation and Transplantation

Mustafa Al-Mousawi

The important problems in the field of donation and transplantation led to a WHO EMR Informal Regional Consultation on Developing Deceased Donor Donation, a consultation held in Kuwait in November 2006. The contents of the statement derived from this consultation (Kuwait Statement) include the following recommendations.

1. To support the development and expansion of organ and tissue donation from deceased donors in all countries of the Eastern Mediterranean Region.
2. To oppose commercialism and transplant tourism.
3. To support identification of the procedural steps to develop organ and tissue donation from deceased donors, which should include:
   a. development of a national legal framework
   b. establishment of national organizations.
4. To urge all governments to provide the necessary legal, administrative and financial resources to implement these recommendations through a national transplant authority.
5. To call upon the International Society for Nephrology, the Transplantation Society and the Global Alliance for Transplantation to take note of and communicate to partners the principles contained in this Statement.

Participants in this consultation will communicate the Kuwait Statement to their respective ministries of health and bring it to the attention of the next session of the WHO Regional Committee for the Eastern Mediterranean. In this region the Middle East Society for Transplantation (MESOT), in partnership with WHO and using the WHO Guiding Principles on Transplantation, will support countries in the implementation of the Kuwait Statement on Cell, Tissue and Organ Transplantation.

The Third World Day for Organ Donation and Transplantation (WDODT), to be held in Kuwait on 28 October 2007, aims to encourage organ donation in the Middle East and to discuss obstacles and problems related to transplantation. Plans for this third WDODT include the following:

1. A public campaign leading up to the day.
2. The invitation of regional and international transplant experts.
3. The involvement of officials from ministries of health and education.
4. GCC transplant committee and MESOT
5. Second Middle East Transplant Games.
6. GCC transplant seminar.

KEY POINTS:
The World Transplant Games aims to increase organ donation and to aid the full physical, psychological and social rehabilitation of transplanted patients. A positive impact of the WTG on the mass media has turned into a positive impact on the number of transplants performed.
review of the first, second and the forthcoming third World Day were discussed. The “Kuwait Statement” of October 2007 was reviewed in support of cell, tissue and organ donation.

GUIDING PRINCIPLES ON TRANSPLANTATION

Updated Guiding Principles Towards a Global Common Attitude to Transplantation

Luc Nöel

The WHO Guiding Principles (GPs) on Transplantation are intended to provide an orderly, ethical and acceptable framework which can serve as the basis for regulation. Consistency of the GPs should be maintained by preserving the fundamental content of the 1991 version. However, it should incorporate new provisions that are urgently needed in response to the current trends in transplantation.

The headings of GPs to be discussed during the meeting are listed below.

1. Consent for deceased donation.
2. No conflict for physicians.
3. Deceased and live consenting donors. Diverging opinions. Living unrelated donation raises concerns on the motivation and the possibility of coercion and donor recruitment.
4. Minors and incompetent persons, being aware of comprehensive care improvements on validated medical practices.
5. No sale or purchase.
6. Promotion of donation but no advertising or brokering.
7. Physician responsibility on origin of transplant material.
8. Justifiable professional fees.
10. Quality, safety and efficacy of procedures and transplants.
11. Transparency and anonymity.

It is expected that a Global Forum on Transplantation will be initiated to formulate a common global attitude to transplantation.

Based on previous communications and prior discussions of areas of divergence, a priority for discussion is given to GPs 3, 4 and 5.

Paramount principles:

- respect of the person as an individual
- CTO transplantation is a global affair. Whatever happens in one country can affect the global transplantation community
- in the developing world, in the absence of a comprehensive regulatory framework, the WHO GPs for Transplantation are often used as regulations or laws to apply to transplantation
Guiding Principle 5

Cells, tissues and organs should only be donated freely and without monetary payment or any fungible gift or reward. The sale of cells, tissues and organs for transplantation by living persons, or by the next of kin for deceased persons, should be banned. The prohibition of the sale or purchase of organs does not affect covering the costs for reasonable and verifiable expenses incurred by the donor, including loss of income, or the payment of other expenses relating to the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Highlighted comments on GP 5:

- altruistic donation should be stressed and considered a priority
- it is important to understand the “motivation” of the donor and the relationship of the donor to the recipient
- the Saudi Arabian Living Unrelated Kidney Donation Programme to increase transplantation activity within this country was discussed in detail, specifically with regard to rewarded gifting by the Government
- it is important to establish the difference between reimbursement of expenses and monetary gain, especially important for living donors
- try to use a term other than 'reward' such as 'incentive'
- compensation should include the cost of donation to the donor, as well as the risk of donation for the donor (in Australia, bone marrow donors are provided with life insurance while they are participating in the donation process)
- what is recipient payment? Where is the line drawn between payment and reward? What is acceptable?
- in the developing world, in the absence of a regulatory framework, it is crucial to emphasize altruism and non-commercialisation of transplantation. Governments without a comprehensive regulatory framework should put in place systems to protect the donor
- in the developing world there has been sensitivity to the public versus private sectors. In the private sector it is important to clarify who is going to pay for the transplantation and who is responsible for monitoring activities
- lack of a definition of “transplant tourism”
- the GPs could be used as a global standard with the objective of stopping international commercialisation of transplantation

Include the concept of an authority responsible for overseeing monetary conditions to ensure that no monetary payment or fungible gift or reward is exchanged (e.g. government authority or designated organization and not necessarily compensation provided by the government). Use the term 'altruism'.

27
Include the concept of recipient purchase.

Guiding Principle 3

Donation from deceased persons should be preferred. It should be developed to its maximum therapeutic potential. Donation from live donors is an acceptable option when the donor’s informed and voluntary consent is obtained, when donor care is assured, when the potential untoward consequences of the donation are unlikely to disadvantage the remainder of the donor's life and when the donor's follow-up care is organized. Such live donors should be legally competent, be sufficiently informed to be able to understand and weigh the risks, benefits and consequences of donation, and be acting voluntarily and free of any undue influence and pressure.

Highlighted comments on GP 3:

- a suggestion regarding changes of format made to emphasize “live donors” in the Guiding Principles
- it is not acceptable for the recipient to purchase or pay for cells, tissues or organs
- emphasis on the importance of the long-term follow up of the live donor and recipient
- other issues regarding living donors:
  - some comments related to the need to stress the difference between related and unrelated donation, establishing that donation from related donors should be preferred, although unrelated living donation could be considered an acceptable option. Besides, the concept of related living donor, also included should be the genetic and emotional relationship, although a definition or limit on what is considered genetically and emotionally related is needed
  - as a final comment, it is not clear whether the issue of the unrelated versus related donor should be included in GP 3 itself or as a comment
- “informed consent” is a general statement. There was a suggestion to review “complete and specific informed consent”

Guiding Principle 4

No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than in rare exceptions. Specific measures should be in place to protect the minor and, wherever possible, the minor’s assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

Highlighted comments on GP 4:

- the Australian law distinguishes between renewable and non-renewable tissues. It is suggested adding this as a commentary to the GP but, in discussions, it became apparent that the definitions are not clear
- A point of divergence was on including other vulnerable groups (i.e. unde-privileged) in the GP. It was finally suggested adding this item as a comment to GP 4 or GP 5
- Transplantation with minors should be an exception to the rule, e.g. identical twins and bone marrow transplantation
- The "Vancouver Live Donor Forum" includes a statement on minor donation and also considers the exceptions of identical twins and bone marrow transplantation. It was suggested ensuring that the WHO GP and the Vancouver statement do not contradict each other

Guiding Principle 6

Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal should be encouraged. Advertising the need for or availability of cells, tissues or organs with a view to offering or seeking payment to individuals for their cells, tissues or organs or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

Highlighted comment on GP 6:

- Besides physicians and other health professionals, other individuals (middlemen and vendors) enabling transplantation commercialisation should be mentioned in GP 6 or in the commentary

Guiding Principle 7

Physicians and other health professionals should be prohibited from engaging in transplantation procedures unless they have established that the cells, tissues or organs concerned have not been obtained through exploitation or coercion of, or payment to, the donor or, in the case of deceased donors, the next of kin.

Highlighted comments on GP 7:

- An addition to GP 7 was suggested as follows: “Physicians and clinics should not refer patients to transplant facilities at home or abroad that trade in such organs and tissues and must not seek or accept payment for doing so”
- Concerns were raised regarding clinical practice in caring for post-transplantation patients who have acquired their transplants through commercial avenues and whether this practice is in conflict with GP 7. Clarification was made that the transplant procedure, as reflected in the GP, may refer to the surgical procedure and not to the post-transplant care. It was suggested adding a comment clarifying this issue
Guiding Principle 8

All persons and facilities involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds a justifiable fee for the services rendered.

Highlighted comments on GP 8:

- it was suggested adding a paragraph as follows: “Cells, tissues and organs donated in the expectation that the resources would be distributed on the basis of need and altruism should not be denied to patients who are unable to pay”
- concern was raised about this concept being covered in GP 9

Guiding Principle 10

Quality of care, safety and efficacy of procedures are mandatory for donor and recipient alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for both the donor and the recipient in order to document the benefit and harm for recipients and any harm to living donors.

The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, has to be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance with adverse events and reactions reporting.

Highlighted comments on GP 10:

- risks to patients who are not recipients of organs, etc. (life-saving, emergency nature) should be recognized
- necessary cross-boundary circulation of haematopoietic stem cells is a model of need for international standards and collaborative systems (scientific, professional bodies)
- need to explain 'traceability' better (beyond what is said in paragraph 39) and maybe describe the need for a common and harmonized system

Guiding Principle 11

While transparency of system organization, donation and transplantation activities and clinical results is necessary in donation and transplantation and should be mandatory, the personal anonymity of donors and recipients must always be protected.
Highlighted comments on GP 11:

- transplantation would be better protected if it welcomed oversight to highlight concerns before they became a problem. This concept should be reflected in the GP
- maximize the availability of data, as a basis for scholarly and government oversight is needed
- removing “while” puts the emphasis on transparency being mandatory, which is good

Additional points for consideration on GP

- for developing countries it is very important to reflect in the GP the need to prevent diseases leading to the need of a transplant. This is an issue to be emphasized in the GP in the context of the stated shortage of organs
- it was suggested adding a recommendation on the need for a national transplant organization (transplant services and allocation). It was discussed whether it would be better to reflect this recommendation in a GP or in a separate report or in a WHA resolution
- the draft GP resulting from the meeting will be further circulated to participants and improved through exchanges. A draft of the final version of the GP resulting from this process will be attached as Annex 3 to this document

A GLOBAL FORUM FOR A COMMON GLOBAL ATTITUDE TO TRANSPLANTATION (GFT)

The need for the creation of a GFT was identified early in the consultation process that followed Resolution WHA 57.18. As practices are rapidly evolving in transplantation, with the progress of science and societies, unethical practices are also changing. For example, transplant tourism moves from country to country and unscrupulous individuals are devising new ways to exploit vulnerable patients and donors. There will be a need to react to the findings of the GKT, recognize and promote models, and identify and denounce unacceptable situations. The GFT would bring together all stakeholders in transplantation. It would facilitate information exchange, analyse the current situation in transplantation worldwide, in particular from the GKT, and identify issues and potential solutions. As a result, GFT would produce advice and recommendations to WHO. The GFT would be supported by the WHO secretariat. WHO would ensure broad dissemination of the GFT's findings.

The GFT is a necessary way to maintain a common global understanding of issues in transplantation as this activity depends on people's traditions, culture and religious beliefs, in addition to the level of education and information, yet transplantation is global with international movement of cell and tissues for transplantation and organ transplant tourism. This international circulation can be positive resulting in improved access to transplantation therapy as well as destructive with the exploitation of vulnerable groups, in particular citizens of poor countries as a source of organs. Break out groups were formed and charged with exploring the objectives, participants and methods of work of the GFT to best serve the global community.

Objectives of the GFT

The GFT will have three main functions:
1) As a primary function it will provide advice on ethical issues arising from practices in donation and transplantation. The GFT would be particularly well placed to discuss differences in practices, recognize the validity of differences in understanding owing to varying social, cultural and economic backgrounds, and to encourage and seek consensus on a global approach. The GFT would specifically debate three areas: transplant tourism, allocation and equity and the priority of transplantation in a national healthcare strategy. It would discuss comments and maintain ethical guidelines including the Guiding Principles on Transplantation on the basis of facts and data provided in particular by the GKT and the ONT observatory of global practices in transplantation. The GFT would therefore be an essential tool to foster global harmonization of perception and understanding and will contribute to a common global attitude to transplantation.

2) Information sharing and networking would be the second function of the GKT. The GFT would develop communications with stakeholders and contribute to the information of professionals and the lay public. It will contribute to improving knowledge of the difference between cultures, traditions and religions as regards donation and transplantation. It would facilitate exchanges between scientific and professional societies and health authorities as well with the public.

3) It will encourage donations from deceased donors, particularly in countries where cultural, traditional or religious barriers are strong, through careful initiatives, in particular putting forward success stories in similar contexts.

Possible participants in the GFT

Participants in the GFT would represent all regions of the world, all level of development and a variety of backgrounds in order to justify the broad representation of the GKT.

Possible participants were categorized as follows:

- Individual experts including selected members of the WHO Expert Advisory Panel and representatives of WHO Collaborating Centres in transplantation
- Representatives of medical and scientific societies. The following were named but the list is not exhaustive and not all named societies could be invited to the GFT meeting:
  - Cells: i.e. Foundation for the Accreditation of Cellular Therapy (FACT), Joint Accreditation Committee (JACIE), International Society for Cellular Therapy (ISCT), European Blood and Marrow Transplant (EBMT)
  - Tissues: i.e. American Association of Tissues banks (AATB), Eye Banks of America Association (EBAA), European Eye Bank Association (EEBA), European Association of Tissue Banks (EATB), dental associations
  - Organs: i.e. United Network for Organ Sharing (UNOS), Eurotransplant, Transplant Information Services (TIS), Canadian Society of Transplantation (CST), European Society of Organ Transplantation (ESOT), American Society of Transplantation (AST), Asian Society of Transplantation (AST), Middle East Society of Transplantation (MESOT), the International Society for Heart and Lung Transplantation (ISHLT), International Liver Transplantation Society, European Transplant Coordinator Organization (ETCO), North American Transplant Coordinator Organization (NATCO)
- Policy makers and regulators, ministries of health, government agencies, UK Transplant, Agence de la Biomédecine and regulatory authorities, i.e. US Food and Drug
• Processors and manufacturers: i.e. Lifenet, Héma-Quebec, Musculoskeletal Transplant Foundation (MTF), heart valve and skin foundations, BIS Foundation
• Representatives of patients' association, recipients and candidates, of donors and donors' families
• Other NGOs: Juvenile Diabetes Research Foundation International (JDRF), World Marrow Donors Association (WMDA), Kidney Disease Improving Global Outcomes (KDIGO), Fairtransplant Foundation for the World Day of Organ Donation and Transplantation
• Ethicists, jurists, representatives of civil society
• Representatives of the pharmaceutical industry and for-profit stakeholders in general terms including commercial tissue banks. Concerns about conflict of interests were voiced, but there was final consensus on their attendance at the Global Forum with representatives of their umbrella associations as they would not be involved in the decision making. It was considered as unrealistic to develop a global attitude without taking them into account
• Representative of health insurance, either from government-run social security systems or from umbrella associations of private insurance/industry, were seen as useful components A number of participants in the GFT would have to be Observers.

Possible structure and method of work of the GFT

Possible structure of the GFT:
The GFT is foreseen as an ongoing body working through electronic communication and with regular plenary meetings felt to be necessary to maintain the GFT's cohesion. However, such plenary meetings would probably have to be held every two years in order to limit costs. An executive committee (with the six WHO regions being represented) will set the agenda and carry work forward between Forum meetings. Working groups on specific topics such as transplant tourism and possible regional sub-committees (without suggesting separate standards) will likewise proceed through virtual meetings and report to the GFT members.

The relationship to WHO will need to be clarified. The GFT could be independent or an extension of WHO. Likewise participants raised the question of the sustainability of the GFT as WHO’s interest in the future of the GFT may change in the coming years. At this point it was outlined that WHO would be the Secretariat, structured to facilitate the dissemination of information (to health authorities, the public, scientific societies and professional organizations)

Methods of work for the GFT:
The GFT intends to be principally, but perhaps not totally, a 'forum' for discussion and sharing of information. Some topics are best treated informally (talking) while others will require more formal deliberation, possibly structured on the basis of a concept paper, and action. The executive committee will prepare the agenda with the secretariat (WHO).

Priorities for the GFT

The priority for the GFT was identified as increasing access to safe and efficacious transplantation. This implies encouraging donations through contributing to public and professional education and promoting deceased donor donations. It mandats maintaining equity
in the allocation of organs to preserve trust in the system and the provision of appropriate resources. In the developing world, minimum requirements for facilities, infrastructure development and access to maintenance treatments are necessary to the success of organ transplantation. Research into the practice of organ transplantation in constrained resource environments are to be encouraged.

There was agreement that the link between policy activities in transplantation and the effort at preventing diseases leading to end stage organ failure and the need for transplantation must be preserved and developed.

The following topics were identified as likely to evolve rapidly, thus justifying monitoring and regular review:

- **safety and efficacy:**
  - donor protection and safety
  - recipient safety: ensuring long-term follow up of patients. The recipient should not become a recipient again
  - public health implication, whether direct, e.g. spread of transmissible diseases, or indirect, e.g. through resource allocation
  - processing of CTOs to attain increased safety and efficacy
  - CTO transplantation complications and emerging diseases

- **ethical and legal issues:**
  - exploitation of the poor and vulnerable
  - commercialisation
  - unavailability of transplantation in some countries
  - lack of information on risks to potential donors
  - inadequate legal framework and oversight responsibility

- **for the future:**
  - xenotransplantation
  - stem cell transplantation
  - ethical issues and safety

Other suggestions of topics for the GFT:

- Long term graft survival depends on the observance of immunosuppressive treatment. Even with state of the art immunosuppression, the life of a kidney transplant is limited to some 15 years as a mean by chronic rejection. Continued access to immunosuppressive drugs and thorough compliance with the treatment are evidently prerequisite for a successful transplantation. Therefore the lack of, or inefficiency of, immunosuppression is an issue of concern. Likewise the current research on immunotolerance and other approaches aiming at minimizing immunosuppression need to be encouraged.

- The economic aspects of transplantation need to be considered in the context of the diseases leading to end stage organ failures. The costs of lack of access to transplantation and of alternatives to transplantation needs to be balanced not only with the cost of transplantation surgery but also of providing appropriate recipient and donor care. The investment in transplantation should include the development of a donation organization to maximize the therapeutic use of organs from deceased donors. From a public health standpoint it make sense to consider diseases leading to end stage organ failures in a comprehensive manner from prevention to transplantation.

To the of question whether similar fora already existed in WHO and if their experience could not be useful to the GFT, the response was that there were several partnership initiatives but
primarily focused on producing outcomes. A relevant example is the Global Collaboration on Blood Safety (GCBS) supported by WHO. Silvano Wendel, Vice-Chairman of the GCBS, provided details of its structure and functioning. Agencies all over the world participate in a yearly meeting. It has a planning group with 12 members. It produces recommendations every year and could be considered very comparable to the projected GFT. Industry is invited and everyone is free to talk. Some of the GCBS products (not all) have been successful. Experience has shown that the GCBS achieves results when well focused on specific points.

**LAUNCH OF THE GLOBAL DATABASE FOR DONATION AND TRANSPLANTATION (GDDT)**

The GDDT was opened to Member States and to the press from the Spanish Ministry of Health in Madrid.

J. Martínez Olmos (Ministry of Health) emphasized the sincere and active cooperation of WHO as one of the key issues of outdoors policy of Spain in health. The fact that the ONT is an organizational reference for the world on donation and transplantation has made this field a preferential one for this cooperation. Today is a special day since the GDDT is the result of the efforts performed within this cooperation.

Rafael Matesanz gave an overview of the global data available on transplantation activities across the world. The GDDT has been developed by the ONT as a result of cooperation between the Spanish Ministry of Health and WHO. It is a physical and real tool to collect accurate data on donation and transplantation activity throughout the world. It is therefore expected to be a reference tool at international level and foster progress and transparency.

**FINAL RECOMMENDATIONS OF THE CONSULTATION**

1. The creation of a Global Forum on Cell, Tissue and Organ Transplantation (GFT) defined more as an ongoing structured exchange between the various stakeholders in transplantation rather than a meeting regularly held, is considered critical for the safety and quality of transplantation and global harmonization. The GFT would facilitate information exchange, analyse the current situation in transplantation worldwide, in particular from the GKT, and identify issues and potential solutions. Its secretariat should be undertaken by WHO. Terms of reference of the GFT should be explored by WHO.

2. Member States are invited to contribute with their data to the GKT in particular through the Global web Portal on transplantation with the Global Database on Donation and Transplantation established by WHO and ONT. With the support of Member States and professional societies it constitutes an essential tool to ensure provision to the public, professionals and policy makers of accurate, comprehensive data on CTO transplantation on an ongoing basis.

3. Member States and appropriate scientific and professional societies should undertake initiatives to achieve national and/or regional self-sufficiency in CTOs for transplantation
primarily through increasing donations from deceased donors as the GDDT confirms a low incidence of deceased donors for organ donation on a worldwide basis.

4. Before engaging in donation and transplantation activities Member States should enact and implement the necessary legal framework for donation and transplantation activities, in particular to protect donors, recipients and public health.

5. Member States in countries where infrastructure, education and financial resources may not support a transplant system should make it a priority to undertake a comprehensive evaluation of the capacity to initially achieve a successful cornea, kidney and liver transplantation programme including tertiary care, support laboratory, diagnostic imagery resources and the ability to ensure proper maintenance treatment, including access to immunosuppressive treatments.

6. WHO should engage in the process of identifying a global common glossary and data dictionary to simplify comprehensive data collection and communication. Terms like "transplant tourism", "genetically related individuals", "emotionally related" need to be explained and would benefit from agreed definitions.

7. WHO should facilitate the establishment of a common universal basis for a coding system for CTOs for transplantation that would use a global common basic nomenclature of transplants, including a system allowing a coded unique identification of the donor and of the responsible establishment for the transplant with the country of origin as well as any other information relevant to the safety, quality and efficacy and also ethics of CTO transplantation.

8. WHO should encourage and support research on medical and paramedical education relevant to CTO donation and transplantation, how to increase deceased donations in various cultures, religions and traditions and on appropriate follow up and maintenance of recipients and donors, including access to affordable immunosuppressants.

9. Member States and WHO should collaborate to better define transplant tourism practices and their ramifications, to improve data collection on this prohibited international activity, to identify victims, both recipients and donors, and to ensure their access to proper care, to enforce measures to curb transplant tourism at the global level, including enactment and enforcement of a legal framework at the country level, encouraging self sufficiency in transplantation at the national and sub-regional level and prohibiting reimbursement by health insurance of the purchase of organs.

10. Realizing that commercial transplantation is the root cause of trafficking and exploitation of the poor and vulnerable, the possible value of a binding international document that would prohibit financial gain from the human body or its parts should be assessed. Such a document could reinforce the responsibility of governments in enacting and implementing national laws to protect their countries and prevent preying on the vulnerable. It would carry more strength than the Guiding Principles. It would also give a further impetus to the development of community-based CTO donation programmes towards national or sub-regional self sufficiency.
Second Global Consultation on Critical Issues in Human Transplantation: Towards a Common Global Attitude to Transplantation

28-30 March 2007, Geneva HQ, Switzerland (Executive Board Room)

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## Annex 2

**Second Global Consultation on Critical Issues in Human Transplantation: Towards a Common Global Attitude to Transplantation**

28-30 March 2007, Geneva HQ, Switzerland (Executive Board Room)

**Draft Programme of Work**

### Day 1: Wednesday 28 March

<table>
<thead>
<tr>
<th>Time</th>
<th>Session and Details</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
<td>Lucy OKOT-ODOKOJOJ Chris FAIVRE-PIERRET</td>
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<tr>
<td></td>
<td><strong>Opening Session</strong></td>
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<tr>
<td>09:00-09:10</td>
<td>Welcome and opening remarks</td>
<td>Howard ZUCKER Assistant Director-General Health Technology and Pharmaceuticals</td>
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<tr>
<td>09:10-09:20</td>
<td>Objectives of the meeting</td>
<td>Steffen GROTH Director Department of Essential Health Technologies</td>
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<tr>
<td>09:20-09:40</td>
<td>Introduction of Participants</td>
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<td>09:40-09:45</td>
<td>Election of Chairpersons and Rapporteurs</td>
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<tr>
<td></td>
<td><strong>Background and Update</strong></td>
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<tr>
<td>09:45-10:05</td>
<td>WHO in Transplantation: A look back and the way forward</td>
<td>Luc NOËL</td>
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<tr>
<td>10:05-10:15</td>
<td>Global Situation. The Global Knowledge Base on Transplantation</td>
<td>Mar CARMONA</td>
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<td>10:15-10:35</td>
<td>Global Situation. The ONT-WHO Global Observatory of Transplantation</td>
<td>Blanca MIRANDA</td>
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<td>10:35-11:00</td>
<td>Tea and coffee break</td>
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<tr>
<td>11:00-11:15</td>
<td>Global Situation. Mapping Transplant Tourism</td>
<td>Yosuke SHIMAZONO</td>
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<td>11:15-11:45</td>
<td>General Discussion</td>
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<td>Country Progress, Legislative Framework</td>
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<td>11:45-11:55</td>
<td>China</td>
<td>Jiye ZHU</td>
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<td>11:55-12:05</td>
<td>Pakistan</td>
<td>Adib RIZVI</td>
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<td>12:05-12:15</td>
<td>Philippines</td>
<td>Leonardo DE CASTRO</td>
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<td>12:15-12:30</td>
<td>General Discussion</td>
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<tr>
<td>12:30-14:00</td>
<td>Lunch</td>
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<td></td>
<td>Increasing Donations &amp; Access</td>
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<td>14:00-14:10</td>
<td>USA</td>
<td>James BURDICK</td>
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<tr>
<td>14:10-14:20</td>
<td>Spain</td>
<td>Blanca MIRANDA</td>
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<td>14:20-14:30</td>
<td>Saudi Arabia</td>
<td>Faisal SHAHEEN</td>
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<td>14:30 - 14:40</td>
<td>Tunisia</td>
<td>Mohamed BEN AMMAR</td>
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<td>14:40-14:50</td>
<td>Mongolia</td>
<td>Noosgoi OYUNTSETSEG</td>
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<td>15:00-15:10</td>
<td>Mali</td>
<td>Mahamane MAÏGA</td>
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<td>15:10 - 15:30</td>
<td>General Discussion</td>
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<td>15:30-16:00</td>
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<td>Cell and Tissue Services</td>
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<td>16:00 -16:15</td>
<td>Safe and effective cell and tissue transplantation services</td>
<td>Deirdre FEHILY</td>
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<td>16:15 -16:30</td>
<td>Ethical issues in cell and tissue donation and transplantation</td>
<td>Annette SCHULZ-BALDES</td>
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<td>16:30 - 16:45</td>
<td>General Discussion</td>
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<td>16:45 -17:00</td>
<td>From key safety requirements to harmonized description</td>
<td>Paul DUBORD</td>
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<td>17:00-17:15</td>
<td>International harmonization and standardized coding</td>
<td>Naoshi SHINOZAKI</td>
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<td>Advocacy for the Public and for Policy Makers</td>
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<td>17:15-17:25</td>
<td>World Transplant Games</td>
<td>Maurice SLAPAK</td>
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<td>17:25-17:35</td>
<td>The Second World Day of Donation and Transplantation, Buenos Aires 2006</td>
<td>Armando PERICHÓN</td>
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<td>17:35-17:45</td>
<td>The Kuwait Statement and the Third World Day of Organ Donation and Transplantation</td>
<td>Mustafa AL-MOUSAWI</td>
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<td>Summary of Day 1</td>
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<td>Guiding Principles on Transplantation</td>
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<td>09:15-09:45</td>
<td>Updated Principles Towards a Global Common Attitude to Transplantation</td>
<td>Luc NOËL</td>
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<td>11:00-12:30</td>
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<td>A Global Forum for a Common Global Attitude to Transplantation</td>
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<td>14:00-14:10</td>
<td>Introduction to Breakout Groups</td>
<td>Luc NOËL</td>
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<td>14:10-15:30</td>
<td>Breakout Groups: Global Forum on Transplantation (GFT)</td>
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<td>Group 1: Objectives of the GFT</td>
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<td>Group 2: Who could be participants in the GFT</td>
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<td>Group 3: Possible structure and method of work of the GFT</td>
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<td>Group 4: Priorities for the GFT</td>
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<td>Presentation: Breakout Group 4</td>
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<td>09:15 - 10:00</td>
<td>Draft Recommendations</td>
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<td>10:00 - 10:30</td>
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<td>11:00 - 12:00</td>
<td>Final recommendations</td>
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<td>12:00 - 12:20</td>
<td>Launch of the Global Observatory for Donation and Transplantation (Duplex with Madrid)</td>
<td>Minister of Health of Spain</td>
</tr>
<tr>
<td>12:20 - 12:45</td>
<td>Conclusions and Closing Remarks</td>
<td></td>
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<tr>
<td>13:00</td>
<td>End of meeting</td>
<td></td>
</tr>
</tbody>
</table>