1. Lack of clear basic definitions in HC/HT transplantation

a. Ownership of the human body, its parts or products is not clearly defined from a legal, economic, cultural and philosophical perspective.

- In many countries, there are no legal frameworks for HC/HT transplantation. Existing frameworks are based on a variety of legal definitions of HC/HT in which tissues may be regarded as organs, specific entities, medical devices or pharmaceutical products. It is important to consider that legal definitions influence processing and distribution of HC/HT as well as oversight of activities involving HC/HT.
- Property rights of HC/HT are inexplicit from a legal perspective. In the deceased in particular, it is not clear whether the HT belongs to the deceased individual, to his or her next-of-kin, or to society.
- From an economic perspective, it is unclear at what point the human body is transformed into a product. When HC/HT products are sold, does this imply the sale of a good with a certain value? Or rather, is a priceless object associated with monetary value through investment of other goods and services, the cost of which is recovered to allow continued supply?

b. The term "donor" is often ambiguous and may refer to either the donor him- or herself, to his or her legal/nominated representative and/or to the donor's next-of-kin.

- While the donor him- or herself is able to decide whether they wish to donate tissue and give informed consent, it is important to acknowledge that in some cases, next-of-kin may know little or nothing about the donor and his or her wishes. And even if they know, next-of-kin do not always decide according to the hypothetical will of the deceased (substituted judgement), but may also take decisions based on their own interests.

In the following, a broad notion of "donor" as the donor him- or herself, to his or her legal/nominated representative and/or to his or her next-of-kin is adopted.

2. Donation and procurement of HC/HT

a. Both living and deceased donation of HC/HT should be voluntary and unpaid.

- Because payment for HC/HT donation may unduly induce donors and will likely result in exploiting or taking of unfair advantage of the vulnerable and poor, donation

of HC/HT from both live donors and from the deceased should be unpaid. However, donors may receive compensation for travel expenses, loss of earnings and/or other expenses actually incurred.

b. The criteria applied in the identification and selection of potential donors should be made explicit and clearly communicated to the general public

- It is important to note that in today's practice, potential donors are not only identified according to medical eligibility: The theoretical number of medically eligible HC/HT donors by far exceeds the number of people who actually donate. This can be either due to potential donors declining consent, or to factors other than medical eligibility that influence donor identification on the part of medical, nursing and/or tissue procurement personnel. Which additional factors influence donor identification in practice frequently remains unclear.
- Donor registries may facilitate a more systematic identification of potential donors, if security and privacy of data can be guaranteed.

c. Procurement of HC/HT should be coordinated with the procurement of organs, if applicable.

- When consent has been given for both organ and HT procurement from a deceased person, priority decisions may be necessary. Should organ or HT procurement have priority? And should a procured organ be used as an organ for transplantation, if medically appropriate, or processed into a profitable HT (e.g. processing of heart valves or the entire heart)? Because the scarcity of organs is more marked than the scarcity of HT, procurement of organs should be generally prioritized over procurement of HT for transplantation.

3. Consent for donation of HC/HT

a. Consent for donation is crucial.

- The body of a living person is not a public good, and the remains of a deceased person are usually not considered a public good either. HC/HT can only be procured after consent for donation has been given either by the person, his or her legal/nominated representative or his or her next-of-kin. If informed consent can be presumed rather than be required as an explicit statement largely depends on public awareness and individual education about HC/HT transplantation and opting out procedures.

- Consent for donation does not justify all clinical practices. In particular, HT procurement in living donors can inflict irreversible and severe harm on the individual. Only safe clinical practices that do not cause serious harm to the individual can be considered for living donation.
- Prior to actual procurement of HT, withdrawal of consent should be possible at any time. In rare cases such as hematopoeitic stem cell donation, however, withdrawal of consent may be highly problematic (e.g. when the recipient is already conditioned), and this should be made clear to the donor.

b. It is a particular challenge to sensitively provide appropriate information on HT procurement, processing, distribution and transplantation when obtaining informed consent from relatives in the deceased donor situation.

- HT procurement, processing, distribution and transplantation are complex and continuously changing procedures, and providing comprehensive information on current practices does not seem appropriate in a situation of grief. Information should rather be given with regard to the donor's informational needs. A sensitive approach by professionals who are educated to work with the bereaved and are both confident and comfortable discussing donation with families is crucial for obtaining valid consent for donation. Follow-up support for the bereaved and their information needs should be addressed in the consent discussion as well.
- It is particularly controversial whether information relating to profit-making should be provided. Some suggest a nuanced approach that distinguishes between involvement of for-profit and not-for-profit organizations in HC/HT processing and/or distribution. It is important to note that profits can be made in both organizations, but are then distributed differently. For-profit organizations generally distribute profits among shareholders while not-for-profit organizations invest surpluses into the improvement of services (but do not distribute surpluses among stakeholders). It is reasonable to assume that the public expects not-for-profit organizations to be involved in HC/HT processing and/or distribution or similar services; however, this is not the case for for-profit organizations. For this reason some suggest that information should be provided about involvement of for-profit organizations but can be withheld when not-for-profit organizations process and/or distribute HC/HT. In any case there can be no valid consent if the consenting party is deceived or donates under the assumption of different conditions, e.g. concerning profit-making or access.

- There is a lack of empirical studies on informed consent for HC/HT donation, in particular with regard to the perspective of the bereaved family (relating to procedural questions of obtaining consent, follow-up of donors and non-donors, etc.).

c. Public awareness and individual education are prerequisites for an effective donation system and for any system presuming informed consent for donation.

d. The discussion about informed consent for HC/HT donation has to take into account existing legal frameworks.

e. Inducements can unduly influence the decision for or against HC/HT donation or constitute a conflict of interest for the next-of-kin.

4. Reporting of testing results

a. It is a sensitive issue whether donor confidentiality of testing results should be maintained even if this affects the health of third parties (e.g. in HIV-positive test results).

The issue should be anticipated as far as possible as part of the consent process. Reporting of testing results is more appropriate if treatment of those affected is possible and likely, and can be legally mandatory if the disease is notifiable.

5. Stewardship of donated HC/HT

a. Tissue and cell establishments have a responsibility to act as stewards of a donation that was entrusted to them, ensuring that the maximum possible benefit for patients results from the donation.

b. The procurement, processing, and distribution of tissues and cells should honour the intentions/expectations expressed in the consent to donate.

- Donors have a right to specify future use of donated HC/HT. Donor wishes should be respected with regard to (1) potential clinical uses – life-saving, life-enhancing or cosmetic – and other uses of donated HC/HT, such as research and training; (2) involvement of for-profit organizations in processing and/or distribution of HC/HT; and (3) potential international circulation and use of donated HC/HT. Directed donation involving discriminatory choices, in particular relating to race and religion, should not be possible.

- In addition to respecting the wishes of individual donors, general priorities for clinical uses of HC/HT should be set in accordance with the general intention of donors to help others in need. One of several reasons to justify oversight and regulation of HC/HT practice is to assure that the choices of organizations involved in HC/HT transplantation are compatible with donor intent.

c. Questions like profit-making have to be discussed in the light of their compatibility with donor's wishes.

6. Profit-making in HC/HT processing and/or distribution

a. The categories "public/not-for-profit" and "private/for-profit" should not automatically be attributed a moral notion; important criteria are stewardship of the donated HC/HT, efficiency, transparency, accountability, fair pricing and responsiveness to health needs of the local or national population and allocation on the basis of clinical need.

- According to most existing legal and regulatory documents, the involvement of for-profit organizations in processing and/or distribution of HC/HT is neither forbidden nor mandatory. HC/HT processing and distribution have many business features, such as technical processing, quality and safety management, distribution of processed HC/HT, etc. Maintaining some market forces in such activities is likely to result in efficient organizational structures and investment in high-quality facilities and/or research and development, and efficient use and high-quality processing of donated HC/HT as well as continuous improvement of services is also an ethical imperative. Therefore, involvement of for-profit organizations in HC/HT processing and possibly distribution can be justified.
- In practice, both not-for-profit and for-profit organizations process and/or distribute HC/HT and some make considerable profits by doing so, depending on national regulations. But the distinction between not-for-profit and for-profit organizations is often blurred because not-for-profit organizations may own for-profit organizations or collaborate with such entities. In addition, not-for-profit and for-profit organizations have to be viewed in the context of national health-care systems. In some countries, tissue establishments do not receive public funding. In other countries, not-for-profit institutions cannot meet existing medical needs and patients may have to rely on services of for-profit institutions to access necessary medical care. This is why

stewardship, efficiency, transparency, accountability, fair pricing and responsiveness to health needs of the local or national population, aiming for equity in access, are often more important for evaluating practices than judging the for-profit or not-for-profit nature of involved organizations.

- It has to be recognized that transparency with regard to profits can be a problem even if official data exist.

b. There may be conflicts of interest between a profit-making orientation and appropriate procurement of and equitable access to HC/HT. For-profit organizations should not be involved in the promotion of donation, the interviewing of donors and donor families or the procurement of tissues, and regulation should aim to minimize conflicts of interests in the distribution of HC/HT.

- While there is consensus that for-profit organizations should not be involved in procurement of HC/HT, there are also concerns that the profit-making orientation of for-profit organizations can compromise equitable access to HC/HT.

c. Involvement of for-profit organizations in HC/HT processing and/or distribution can be acceptable (1) if donors are informed accordingly; (2) if the quality, safety and price of products are at least comparable to not-for-profit organizations; and (3) if the profit-making orientation does not compromise equitable access to cell and tissue services.

d. Autologous/private cord blood banking is not an evidence-based practice today, but a speculative private investment. It should only be offered (1) if proper informed consent is guaranteed, also with regard to the current lack of evidence for the practice; (2) if the cord blood is procured and processed according to safety and quality standards of allogeneic/public cord blood banking; and (3) if cord blood is stored in a sustainable manner.

- A particular concern is a lack of quality control on all levels of autologous/private cord blood banking. As private institutions, these banks are often not subject to common regulatory frameworks. The quality of cord blood stored in private banks may be too uncertain to be actually used by some transplant clinicians.

7. Allocation and international circulation of HC/HT

a. National oversight and prioritization rules are necessary to avoid shortages of HC/HT and to guarantee equitable access to cell and tissue services.

- Patient need should be the most important criterion in the allocation of HC/HT, because donors generally give HC/HT with the intention to help others. Allocation according to patient needs implies that there is a priority of use for life-saving over life-enhancing over cosmetic purposes in transplantation practice. Factors such as scientific evidence, "reciprocity" of services between procurement and processing institutions and waiting time can be equally important factors for allocation of HC/HT. While there is consensus on the need for national oversight and the relevance of explicit allocation criteria, it is controversial how allocation factors should be weighted and whether the scope of allocation rules should be institutional, national, regional, or international. Factors like ethnicity, nationality or religion should not play a role in HC/HT allocation.

- Several factors implicitly affect the allocation of and access to HC/HT and require consideration in the regulation and oversight of these activities. These are most importantly (1) the legal status of HC/HT which defines requirements for processing and thereby affects the balance of for-profit and not-for-profit involvement; and (2) the HC/HT establishments themselves which may process HC/HT according to profitability of different products (e.g. processing of skin into highly profitable acellular dermis products instead of supplying it as minimally processed skin for burn care).

b. International circulation of HC/HT can help address patients' needs on a global level but can at the same time lead to inequities.

- Both for-profit and not-for-profit organizations may experience a conflict of interest between providing access to HC/HT to the local population and making profits by exporting HC/HT internationally. HC/HT should be circulated internationally only if local, national or regional needs are met.

- International circulation or trade of HC/HT does not necessarily imply scarcity of HC/HT.

- Despite the international circulation of HC/HT, transplant tourism also occurs in the field of HC/HT transplantation. Wealthy patients from resource-poor countries go to wealthier countries for HC/HT transplantation services, indicating the need to improve local access to appropriate transplantation services.

c. Building of tissue banking and hospital infrastructures should be fostered in parallel to be able to provide equal access to care.

8. Recipient consent

a. Consent by or on behalf of the recipient must contain information that a planned intervention contains human material. Recipients or their surrogate decision makers also need to be informed about the specific risks of the HC/HT product designated for use, if any, and therapeutic alternatives.

- Internationally, HC/HT recipients or their surrogate decision makers may be unaware that a planned intervention contains human material.

9. Quality and safety

a. There is a need for graduated quality and safety standards for HC/HT transplantation. Minimal quality and safety requirements must be met to guarantee the safety of recipients even if this implies a reduced availability of HC/HT.

- This requirement endorses the WHO Aide Mémoire for National Health Authorities (2006): Access to Safe and Effective Cells and Tissues for Transplantation.

b. Follow-up of living HC donors and HC/HT transplant recipients as well as data collection and scientific outcome evaluation are integral and mandatory elements of any HC/HT transplantation procedure.

c. Traceability should be included in regulatory systems of cell and tissue transplantation.

- Considering that many organ donors are also HT donors, it is desirable for the traceability of organs and tissues to be coordinated in a common surveillance system with universal donor identification numbers.

The information contained in this paper does not necessarily reflect the opinion or the position of each single participant or the institutions they may represent. In particular, the listing of the European Commission's name or of any person acting on behalf of the Commission with this document should not be misconstrued as an endorsement of the information in it unless explicitly noted.

WORLD HEALTH ORGANIZATION

WHO/HTP/EHT/T-2003.1

Ethics, access and safety in tissue and organ transplantation: Issues of global concern

Madrid, Spain, 6-9 October 2003

Report

添付資料－2

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Introductory Note from the Secretariat

This document provides an account of the points discussed and the conclusions reached at a consultation on the ethical, access, and safety issues in tissue and organ transplantation held by the World Health Organization (WHO) in Madrid on 6-9 October 2003. A consultative process was carried out jointly by the Department of Ethics, Trade, Human Rights and Health Law (ETH) and the Department of Essential Health Technologies (EHT) in response to the request of WHO's Executive Board at its 112th session in May 2003 that the Director-General examine this field, including both human-to-human and animal-to-human transplants. This consultative process culminated in the Madrid meeting.

Planning for the Madrid meeting was facilitated by scientific advice from the transplant authorities in France, Spain and the United States of America, among others. The consultation was sponsored by the Ministry of Health of Spain, with additional financial support from the US Department of Health and Human Services (through the Pan American Health Organization/WHO Regional Office for the Americas). We gratefully acknowledge this aid, and in particular we wish to thank the staff of the Organizacion Nacional de Transplantes for their efficient assistance in preparing and supporting the consultation.

This report represents the views of the consultants, not necessarily those of WHO. It has, however, been indispensable in the Secretariat's preparation of a report for the January 2004 session of the WHO Executive Board (Document EB113/14). The present report was prepared by the undersigned, with the efficient administrative and secretarial support of Chris Faivre-Pierret; it is based on a draft written by the meeting's two Rapporteurs, Drs Farhat Moazam and Jeremy Chapman, whose scientific and ethical expertise, remarkable ability to summarize complex materials succinctly and commendable alacrity are gratefully acknowledged.

All the 37 clinicians, ethicists, social scientists and government officials from 23 countries at the consultation were active and helpful participants in the meeting and we thank them all for their individual and collective advice. The Secretariat owes a special debt to meeting's Chair, Dr Carl-Gustav Groth, and co-Chair, Dr Blanca Miranda, for their invaluable contributions both during and after the meeting.

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

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Executive Summary

Transplantation of organs, cells and tissues are now effective therapies across a wide range of both fatal and non-fatal diseases. The excellent survival and success rates of transplantation of organs and cells, such as the kidney, liver and heart or haematopoietic stem cells in immunosuppressed patients, have led to high levels of demand globally. The success rates for transplantation of certain cells or tissues which do not require immunosuppression have also ensured that such procedures are frequently the treatment of choice in the respective therapeutic areas. It is, however, clear that ethically-unacceptable practices occur in a number of countries.

Neither measurements of activity in, nor outcome of, organ, tissue and cell transplantation is available globally. There are data from countries with compulsory registration of transplant activity and there are voluntary registries of some types of transplantation.

Despite the appropriate focus on prevention of disease, the global needs of patients for transplantation are not being met. The demand has outstripped the supply of organs, cells and tissues from both deceased donors and from the altruistic living relatives of patients in need. The alternative treatments and medical support for patients with end stage organ failure, especially renal dialysis, are expensive and limited in many countries. There is also a lack of clinical expertise in some regions and countries and an inability to fund transplantation to some extent in all countries. Thus in all Member States one or more influences prevent the sufficient supply of transplantation therapies and lead to pressure for non-altruistic living donation.

Deceased donation is meeting the needs of transplantation in few, if any, countries. Potential donors are reluctant to commit to donate after death and their families may refuse permission when approached after death. The use of executed prisoners as organ donors in some countries causes great concern that these donations are coerced. Member States employ different models of consent including: presumed consent or "opt out"; required requesting; "opt-in"; and mixtures of these three models. Independently from which specific model is chosen, information and voluntariness are of fundamental importance for the act of post-mortem donation.

Increasing use, over the past ten years, of living donation of non-regenerative organs has extended from kidneys to livers and even to the lung and pancreas in some instances, despite the hope that reliance on living donors could be reduced. There remains great concern that a market in body parts (especially the kidney) has flourished over the past few years with vulnerable persons being tricked or coerced into donating and some recipients travelling with their surgeons to countries where "donated organs may be purchased legally or illegally.

Human cells, human tissues and human organs provide different concerns. Tissues are processed and traded in many Member States by both for-profit and not-for-profit organizations. It is not clear the extent to which donors or their families are aware of the

profit that is created through this trade. Human cells, in particular haematopoietic stem cells, on the other hand, are widely and increasingly exchanged globally between donors and patients through arrangements made by not-for profit organizations which isolate and protect the anonymity of both patient and donor.

Xenotransplantation represents a potential opportunity to ensure a constant supply of organs and tissues for transplantation. However, the scientific hurdles to successful xenotransplantation in humans currently mean that it should only be undertaken under strict clinical trial conditions. There are substantial potential risks to human health from the transmission of xenogeneic infectious agents through xenotransplantation. Careful international monitoring of these clinical trials and of each subject is thus essential to ensuring the safety not only of subjects but also of their families and the broader human population. These issues transcend currently accepted norms of subject consent and medical responsibility for monitoring of the consequences of xenotransplantation.

It is clear that some Member States have not assumed or have been unable to assume an appropriate level of responsibility in each of the areas of transplantation. There are a number of roles for which the World Health Organization is best placed to ensure that minimum levels of human access, safety and ethical practice are adopted universally.

WHO roles could include:

(1) Encouraging the development of transplantation therapies in Member States in an ethically appropriate manner.

(2) Initiating an ongoing programme on transplantation at WHO and establishing a WHO Expert Advisory Panel for transplantation.

(3) Facilitating the development of a core of technical and ethical standards for the management of the safety, quality and efficacy of human material for transplantation that can serve as a model for Member States.

(4) Encouraging Member States to develop a legal framework and national policy and plan on transplantation activities, especially ensuring coordination of the procurement of human material from deceased donors.

(5) Facilitating communication between regulators and providers on the international circulation of human cells and tissues for transplantation, in particular for matched haematopoietic stem cells.

(6) Collecting data on the extent of paid organ, cell and tissue donation.

(7) Creating a global map of the known infectious risks and the safety measures that are applied to donors and donations in different countries and regions of the world.

(8) Helping Member States to develop capacity for national regulatory approaches to quality and safety in particular by encouraging the creation of international support networks.

(9) Encouraging the measurement of the donor outcomes for living donors in different clinical environments, through collaborative global data collections.

(10) Encouraging nations to support consensus on basic principles of xenotransplantation safety and oversight:
- Defining the nomenclature of different types of xenotransplantation.
- Identifying countries in which xenotransplantation occurs.
- Supporting the approach that regulation must be in place in all countries in which clinical trials of xenotransplantation occur.
- Developing general recommendations for obtaining informed consent in situations that may represent a risk to the general public and in which individual rights and the public good may come into conflict.
- Fostering agreement between Member States to control travel for the purposes of xenotransplantation.
- Implementing an international xenotransplant surveillance system.

(11) Rewriting and updating the Guiding Principles, published by WHO in 1991, especially concerning:
- Measures to ensure safe and voluntary altruistic donations from living donors.
- Financial transactions and coercion.

FIFTY-SEVENTH WORLD HEALTH ASSEMBLY WHA57.18

Agenda item 12.14 22 May 2004

Human organ and tissue transplantation

The Fifty-seventh World Health Assembly,

Recalling resolutions WHA40.13, WHA42.5 and WHA44.25 on organ procurement and transplantation;

Having considered the report on human organ and tissue transplantation;

Noting the global increase in allogeneic transplantation of cells, tissues and organs;

Concerned by the growing insufficiency of available human material for transplantation to meet patient needs;

Aware of ethical and safety risks arising in the transplantation of allogeneic cells, tissues and organs, and the need for special attention to the risks of organ trafficking;

Recognizing that living xenogeneic cells, tissues or organs, and human bodily fluids, cells, tissues or organs that have had *ex vivo* contact with these living xenogeneic materials, have the potential to be used in human beings when suitable human material is not available;

Mindful of the risk associated with xenogeneic transplantation of the transmission of known or as yet unrecognized xenogeneic infectious agents from animals to human beings and from recipients of xenogeneic transplants to their contacts and the public at large;

Recognizing that transplantation encompasses not only medical but also legal and ethical aspects, and involves economic and psychological issues,

I

Allogeneic transplantation

1. URGES Member States:

(1) to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material for transplantation and its traceability;

(2) to cooperate in the formulation of recommendations and guidelines to harmonize global practices in the procurement, processing and transplantation of human cells, tissues and organs, including development of minimum criteria for suitability of donors of tissues and cells;

(3) to consider setting up ethics commissions to ensure the ethics of cell, tissue and organ transplantation;

(4) to extend the use of living kidney donations when possible, in addition to donations from deceased donors;

(5) to take measures to protect the poorest and vulnerable groups from "transplant tourism" and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs;

2. REQUESTS the Director-General:

(1) to continue examining and collecting global data on the practices, safety, quality, efficacy and epidemiology of allogeneic transplantation and on ethical issues, including living donation, in order to update the Guiding Principles on Human Organ Transplantation;[1]

(2) to promote international cooperation so as to increase the access of citizens to these therapeutic procedures;

(3) to provide, in response to requests from Member States, technical support for developing suitable transplantation of cells, tissues or organs, in particular by facilitating international cooperation;

(4) to provide support for Member States in their endeavours to prevent organ trafficking, including drawing up guidelines to protect the poorest and most vulnerable groups from being victims of organ trafficking;

II

Xenogeneic transplantation

1. URGES Member States:

(1) to allow xenogeneic transplantation only when effective national regulatory control and surveillance mechanisms overseen by national health authorities are in place;

(2) to cooperate in the formulation of recommendations and guidelines to harmonize global practices, including protective measures in accordance with internationally accepted scientific standards to prevent the risk of potential secondary transmission of any xenogeneic infectious agent that could have infected recipients of xenogeneic transplants or contacts of recipients, and especially across national borders;

(3) to support international collaboration and coordination for the prevention and surveillance of infections resulting from xenogeneic transplantation;

[1] Document WHA44/1991/REC/1, Annex 6.

2. REQUESTS the Director-General:

(1) to facilitate communication and international collaboration among health authorities in Member States on issues relating to xenogeneic transplantation;

(2) to collect data globally for the evaluation of practices in xenogeneic transplantation;

(3) to inform proactively Member States of infectious events of xenogeneic origin arising from xenogeneic transplantation;

(4) to provide, in response to requests from Member States, technical support in strengthening capacity and expertise in the field of xenogeneic transplantation, including policy-making and oversight by national regulatory authorities;

(5) to report at an appropriate time to the Health Assembly, through the Executive Board, on implementation of this resolution.

Eighth plenary meeting, 22 May 2004
A57/VR/8

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Consultation on Transplantation with National
Health Authorities in the Western Pacific Region
7 - 9 November 2005 Manila, Philippines

添付資料－4

The Declaration of Istanbul
on Organ Trafficking and Transplant Tourism

Participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey, April 30–May 2, 2008*

Preamble

Organ transplantation, one of the medical miracles of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. The many great scientific and clinical advances of dedicated health professionals, as well as countless acts of generosity by organ donors and their families, have made transplantation not only a life-saving therapy but a shining symbol of human solidarity. Yet these accomplishments have been tarnished by numerous reports of trafficking in human beings who are used as sources of organs and of patient-tourists from rich countries who travel abroad to purchase organs from poor people. In 2004, the World Health Organization, called on member states "to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs" (1).

To address the urgent and growing problems of organ sales, transplant tourism and trafficking in organ donors in the context of the global shortage of organs, a Summit Meeting of more than 150 representatives of scientific and medical bodies from around the world, government officials, social scientists, and ethicists, was held in Istanbul from April 30 to May 2, 2008. Preparatory work for the meeting was undertaken by a Steering Committee convened by The Transplantation Society (TTS) and the International Society of Nephrology (ISN) in Dubai in December 2007. That committee's draft declaration was widely circulated and then revised in light of the comments received. At the Summit, the revised draft was reviewed by working groups and finalized in plenary deliberations.

This Declaration represents the consensus of the Summit participants. All countries need a legal and professional framework to govern organ donation and transplantation activities, as well as a transparent regulatory oversight system that ensures donor and recipient safety and the enforcement of standards and prohibitions on unethical practices.

Unethical practices are, in part, an undesirable consequence of the global shortage of organs for transplantation. Thus, each country should strive both to ensure that programs to prevent organ failure are implemented and to provide organs to meet the transplant needs of its residents from donors within its own population or through regional cooperation. The therapeutic potential of deceased organ donation should be maximized not only for kidneys but also for other organs, appropriate to the transplantation needs of each country. Efforts to initiate or enhance deceased donor transplantation are essential to minimize the burden on living donors. Educational programs are useful in addressing the barriers, misconceptions and mistrust that currently impede the development of sufficient deceased donor transplantation; successful transplant programs also depend on the existence of the relevant health system infrastructure.

添付資料－5

Access to healthcare is a human right but often not a reality. The provision of care for living donors before, during and after surgery–as described in the reports of the international forums organized by TTS in Amsterdam and Vancouver (2-4)–is no less essential than taking care of the transplant recipient. A positive outcome for a recipient can never justify harm to a live donor; on the contrary, for a transplant with a live donor to be regarded as a success means that both the recipient and the donor have done well.

This Declaration builds on the principles of the Universal Declaration of Human Rights (5). The broad representation at the Istanbul Summit reflects the importance of international collaboration and global consensus to improve donation and transplantation practices. The Declaration will be submitted to relevant professional organizations and to the health authorities of all countries for consideration. The legacy of transplantation must not be the impoverished victims of organ trafficking and transplant tourism but rather a celebration of the gift of health by one individual to another.

Definitions

Organ trafficking is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation (6).

Transplant commercialism is a policy or practice in which an organ is treated as a commodity, including by being bought or sold or used for material gain.

Travel for transplantation is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes **transplant tourism** if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population.

Principles

1. National governments, working in collaboration with international and non-governmental organizations, should develop and implement comprehensive programs for the screening, prevention and treatment of organ failure, which include:
   a. The advancement of clinical and basic science research;
   b. Effective programs, based on international guidelines, to treat and maintain patients with end-stage diseases, such as dialysis programs for renal patients, to minimize morbidity and mortality, alongside transplant programs for such diseases;
   c. Organ transplantation as the preferred treatment for organ failure for medically suitable recipients.