



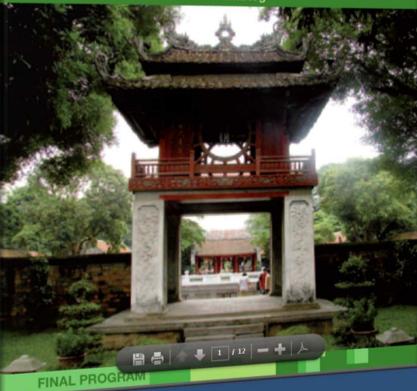
Workshop of the WBMT

in cooperation with the

World Health Organization (WHO)

Hanoi, Vietnam, November 10 - 11, 2011

www.wbmt.org



in collaboration with the





2ND WORKSHOP OF THE WBMT

Salvador - Rabia Brazil



WHO and HCT: Legal and ethical aspects



Ethics



Ethics

The fundamental ethical criterion is respect for the human being, to their inalienable rights, to the person's dignity







- ✓ Recognizing the scientific progress achieved in human organ transplants in many Member States
- ✓ Concerned at the trade for profit in human organs among living human beings
- Affirming that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights and the spirit of the WHO Constitution
- ✓ Commending the measures taken by some Member States to regulate human organ transplants and their decision to develop a unified legal instrument to regulate these operations

REQUESTS the Director-General:

- 1. To study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human transplants
- 2. To report to the Health Assembly on the action taken in this regard.



FIFTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA57.18

Agenda item 12.14

22 May 2004

Human organ and tissue 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;

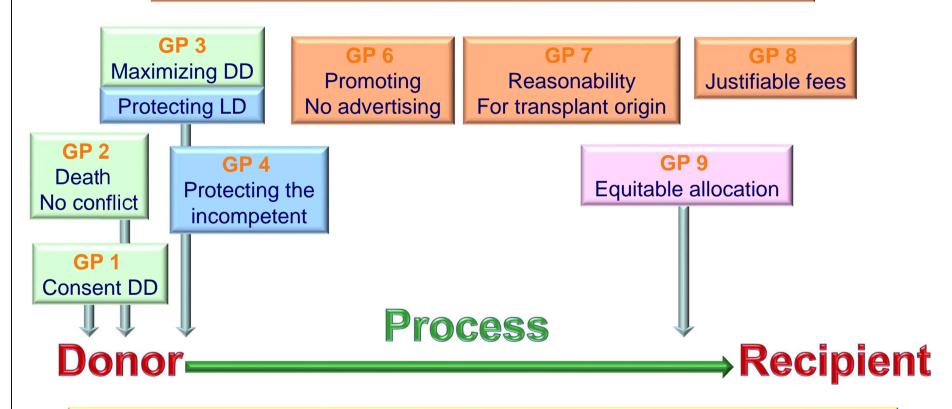




WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION¹

¹ As endorsed by the sixty-third World Health Assembly in May 2010, in Resolution WHA63.22

GP 5 Free donation and no purchase of human transplant as such, but cost &expenditures recoveryt



GP 10 Monitoring long term outcomes. Quality and safety of procedures and products

GP 11 Transparency, openness to scrutiny, anonymity

Guiding Principle 1

Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

- (a) any consent required by law is obtained, and
- (b) there is no reason to believe that the deceased person objected to such removal.

Commentary on Guiding Principle 1

Consent is the ethical cornerstone of all medical interventions. National authorities are responsible for defining the process of obtaining and recording consent for cell, tissue and organ donation in the light of international ethical standards, the manner in which organ procurement is organized in their country, and the practical role of consent as a safeguard against abuses and safety breaches.



Process

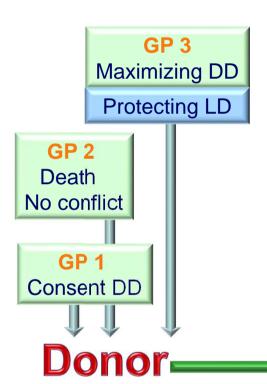
Recipient



Process

→ Recipient

Guiding Principle 3



Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients.

Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.

Commentary on Guiding Principle 3

The Principle emphasizes the importance both of taking the legal and logistical steps needed to develop deceased donor programmes where these do not exist and of making existing programmes as effective and efficient as possible.

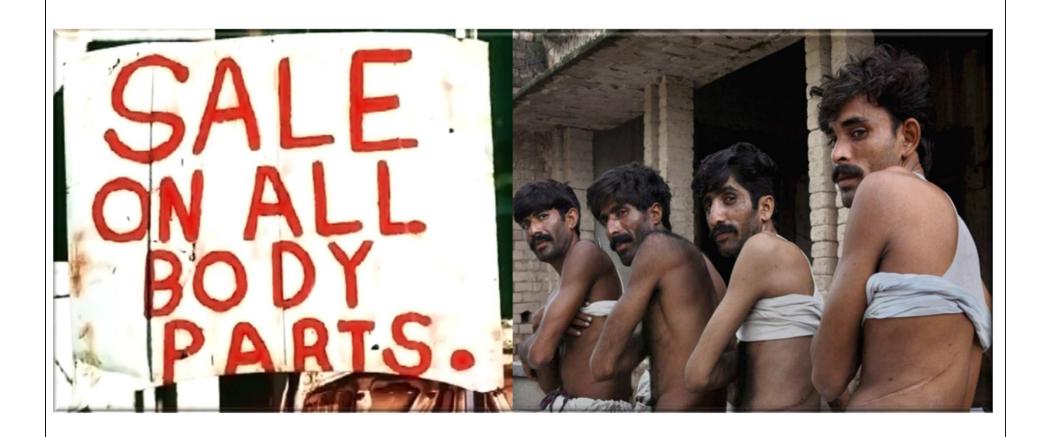
Process







Transplant Tourism & Organ trafficking



Transplant Tourism & Organ trafficking

"Organ trafficking"

- √ financial gain on the organ, tissue or cell as such
- ✓ and/or lack of consent of the donor
- √ and/or transplantation outside of the established system

"Transplant tourism"

involves the donor, the recipient or both crossing national boundaries for the recipient to access a trafficked organ.

Resolution WHA 57.18 and WHA 63.22 endorsing the WHO Guiding Principles for human cell, tissue and organ transplantation



Transplant Tourism & Organ trafficking





Kuwait takes all steps to prevent organ

trafficking

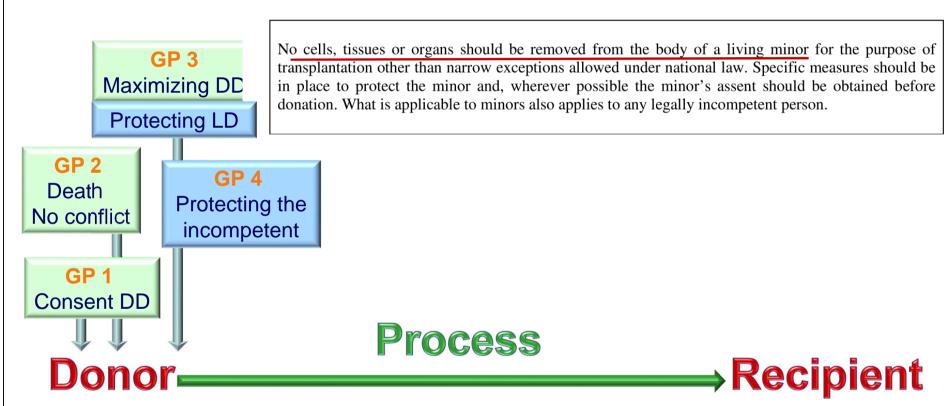


KTS carries out rigorous checks

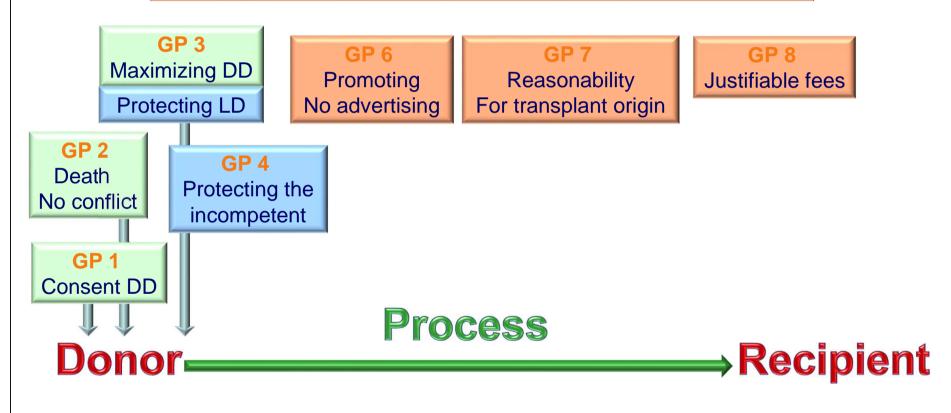
KUWAIT: A recent report by a leading Kuwaiti newspaper has highlighted a dramatic increase in street posters soliciting illegal donations of blood and organs. The posters are found

He added that KTS kidney transplants are performed in Kuwait, while liver transplants are subcontracted to specialists in Saudi Arabia. In each case, the donor's family receives compensation from the given country's Ministry of Health. Reiterating his concerns regarding illegal organ

Guiding Principle 4



GP 5 Free donation and no purchase of human transplant as such, but cost &expenditures recoveryt



Guiding Principle 5

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Guiding Principle 6

Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation.

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.

Guiding Principle 7

Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

Guiding Principle 8

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

To oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking and transplant tourism, including by encouraging healthcare professionals to notify relevant authorities when they become aware of such practices in accordance with national capacities and legislation;

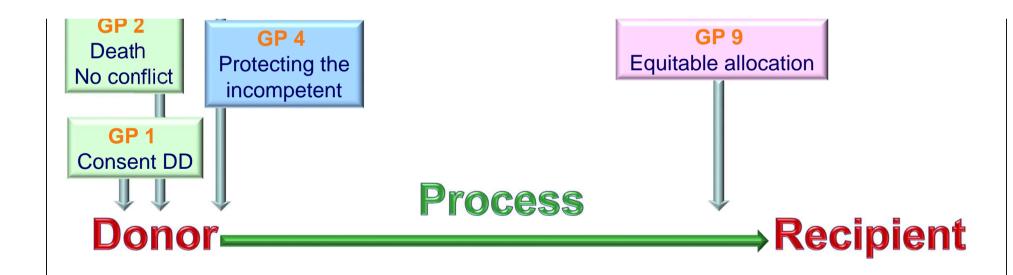
Professionals reporting to authorities

Transplantation professionals have to be promoters of equity



Guiding Principle 9

The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.



Equitable allocation



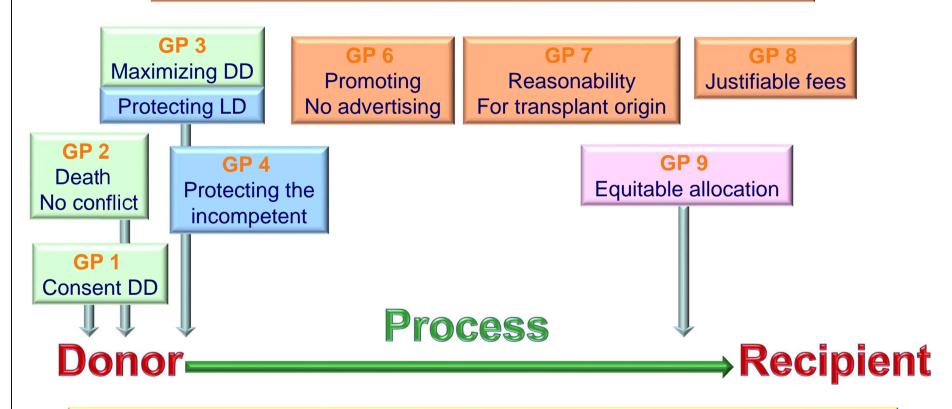
Equitable allocation





Worldwide

GP 5 Free donation and no purchase of human transplant as such, but cost &expenditures recoveryt



GP 10 Monitoring long term outcomes. Quality and safety of procedures and products

GP 11 Transparency, openness to scrutiny, anonymity

Guiding Principle 10

High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

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

Guiding Principle 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

http://www.transplant-observatory.org



World Health Organization



GODT African Americas Eastern Mediterranean Europe South-East Asia Western Pacific Search

Global Observatory on Donation and Transplantation

About us

Global Transplant Information

Facts

Organizational and legal aspects Charts and Tables

Global Transplant Data

Data Reports

Methodology

Uses of Data Entering Data

Newsroom

Events

Press releases

Promoting Donation

Activities and Media Campaigns

Library

Legal documents, guidelines and

other documents

Links

National Transplant Organization Transplant societies

- - - - I-

Journals

Information about Transplant

Registries

Other

Networks

RCIDT - Iberoamerican Council of Donation and Transplantation

GLOBAL OBSERVATORY ON DONATION AND TRANSPLANTATION.



Last global news

Turkmenistan adopts regulations in organ transplantation field. August 2013



WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

Guiding Principle 10

High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

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

Guiding Principle 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.









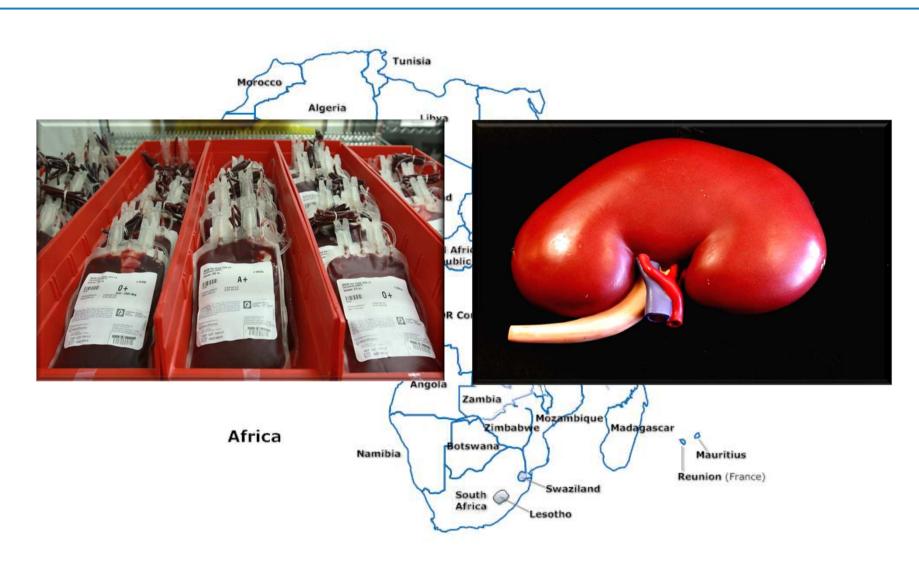
- A database of all types of severe adverse events and reactions that have been reported arising from procurement and processing to clinical application of cells, tissues and organs for transplantation as well as of medical products of human origin used in assisted reproduction technologies.
 - 1. A reference for professionals focused on diagnostic and investigation
 - 2. but also providing evidence for donor selection,
 - 3. A source of information for candidate recipients and living donors
 - 4. A database for further study

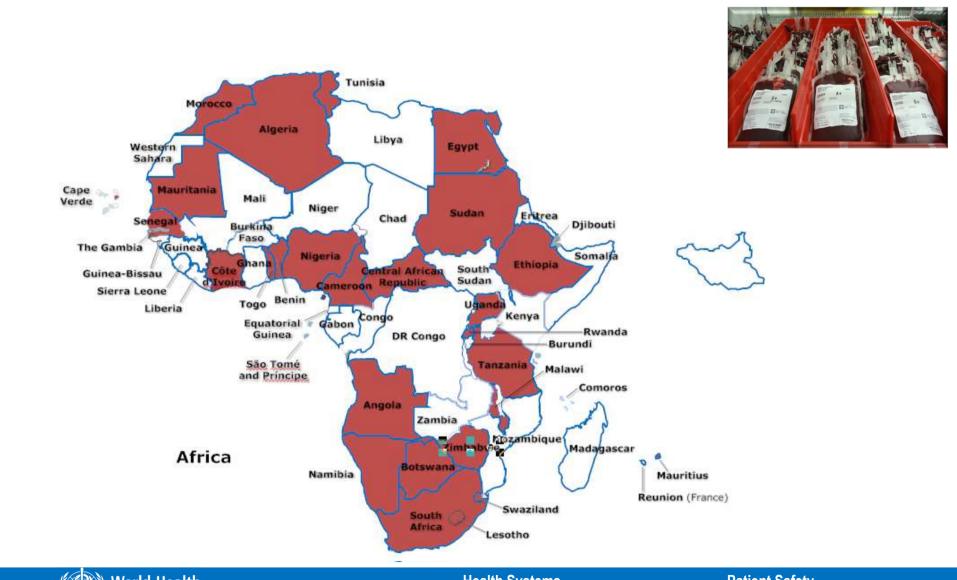
WHO and HCT: Legal and ethical aspects

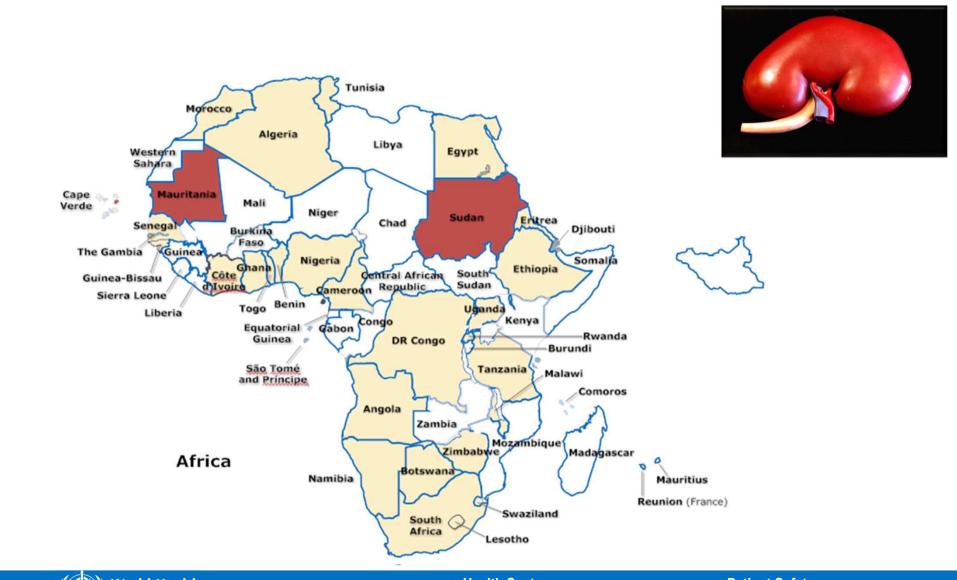


Africa



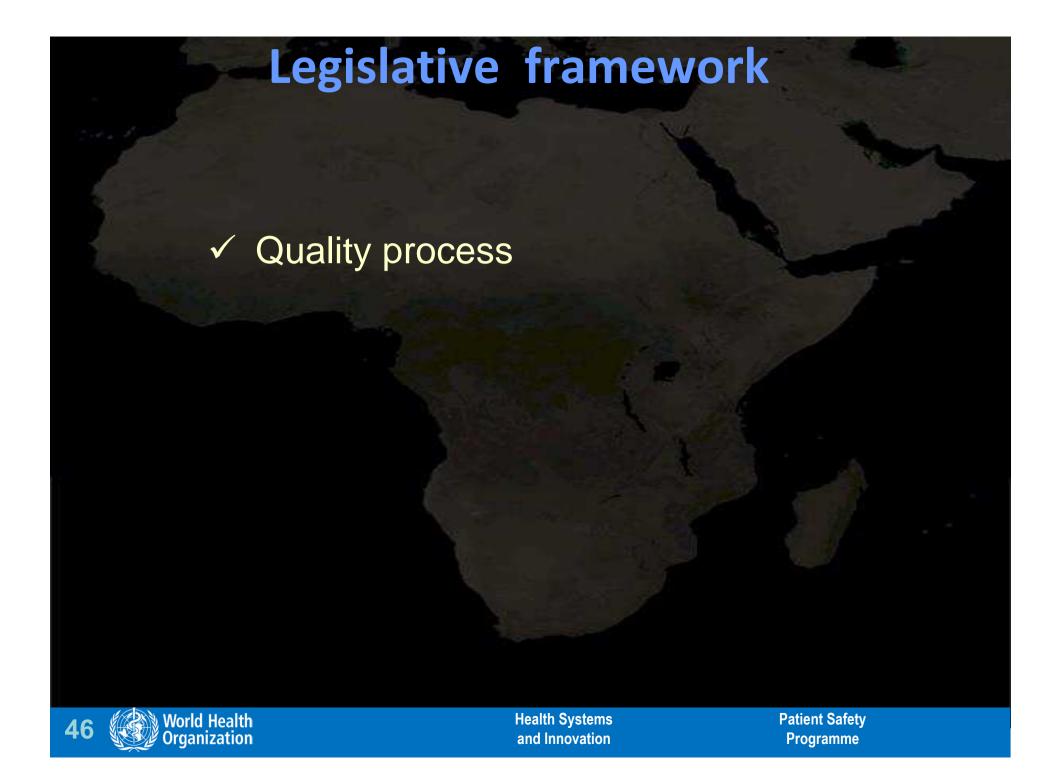






Principles and rights

- ✓ Autonomy
- ✓ No reward
- ✓ Equity
- ✓ Transparency
- ✓ Confidentiality



ORIGINAL ARTICLE

Transmission of Lymphocytic Choriomeningitis Virus by Organ Transplantation

Staci A. Fischer, M.D., Mary Beth Graham, M.D., Matthew J. Kuehnert, M.D., Camille N. Kotton, M.D., Arjun Srinivasan, M.D., Francisco M. Marty, M.D., James A. Comer, Ph.D., Jeannette Guarner, M.D., Christopher D. Paddock, M.D., M.P.H.T.M., Dawn L. DeMeo, M.D., M.P.H., Wun-Ju Shieh, M.D., Ph.D., M.P.H., Bobbie R. Erickson, B.S., Utpala Bandy, M.D., M.P.H., Alfred DeMaria, Jr., M.D., Jeffrey P. Davis, M.D., Francis L. Delmonico, M.D., Boris Pavlin, M.D., Anna Likos, M.D., M.P.H., Martin J. Vincent, Ph.D., Tara K. Sealy, B.S., Cynthia S. Goldsmith, M.S., Daniel B. Jernigan, M.D., M.P.H., Pierre E. Rollin, M.D., Michelle M. Packard, M.P.H., Mitesh Patel, B.S., Courtney Rowland, B.S., Rita F. Helfand, M.D., Stuart T. Nichol, Ph.D., Jay A. Fishman, M.D., Thomas Ksiazek, D.V.M., Ph.D., Sherif R. Zaki, M.D., Ph.D., and the LCMV in Transplant Recipients Investigation Team*

ABSTRACT

BACKGROUND

In December 2003 and April 2005, signs and symptoms suggestive of infection developed in two groups of recipients of solid-organ transplants. Each cluster was investigated because diagnostic evaluations were unrevealing, and in each a common donor was recognized.

The New Hork Times nytimes.com

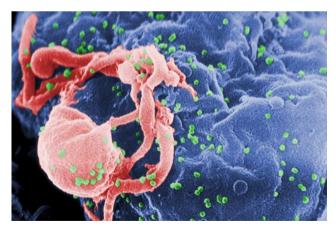
November 13, 2007

Four Transplant Recipients Contract H.I.V.

By DENISE GRADY

Four transplant recipients in Chicago have contracted <u>H.I.V.</u> from an c being spread by organ transplants.

The organs also gave all four patients $\underline{\text{hepatitis } C}$, in what health official simultaneously by a transplant.



The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Informing Candidates for Solid-Organ Transplantation about Donor Risk Factors

Scott D. Halpern, M.D., Ph.D., Abraham Shaked, M.D., Ph.D., Richard D. Hasz, M.F.S., and Arthur L. Caplan, Ph.D.

umented transmission of the human immunodeficiency virus (HIV) through solid-organ transplantation.1 Although transmission of infectious agents through transplantation is rare,2 such cases raise important questions about how informed consent for transplantation should be obtained and about the type of resource that transplantable organs represent.

Should potential recipients be informed about the transplantation is that antibody-based tests to degeneral risks associated with transplantation or tect viruses have poor sensitivity within the first those specifically associated with an identified or- few weeks after infection.2 Although more sensigan? Should the risks engendered by the behavior tive nucleic acid-amplification tests are now used

For the first time in 15 years, there has been doc- she was harmed by not being notified of the donor's above-average risk of HIV and, therefore, was denied the opportunity to decline the donation. Her attorney has declared, "it's up to the patient . . . to make the decision whether to incur the risk."3

BEHAVIORAL RISKS AMONG DONORS

Among the questions raised are the following: A well-known limitation of the safety of organ of donors be treated differently from those asso- in some regions, even these tests do not fully elim-

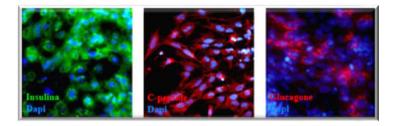


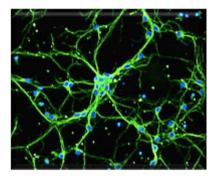
- ✓ Quality process
- ✓ Trazability
- ✓ Biovigilance
- ✓ Prohibition of trafficking



STEM CELLS THERAPY







BUSINESS AND MEDICINE

The Business of Stem Cells

Debora Spar, Ph.D.

made global headlines. Using somatic-cell nuclear the genetic material from a single adult cell. They then stimulated the newly transformed egg cell and prompted it to begin dividing. Several days later, they had produced a line of human embryonic stem cells — the first ever created in a laboratory.

Scientifically, the impact of this procedure was immense. The Korean team had demonstrated the science park focused on stem-cell technology. practical ability to manufacture stem-cell lines from scratch. They had shown that it was physically possible to grow stem cells from the genetic material of a single person and then - theoretically at least - to produce other cells or tissues that would match those of the original donor perfectly. From these identical matches could come whole new ways of treating human illness; nerve cells for patients with Parkinson's disease, brain cells for patients

On February 12, 2004, a team of Korean scientists with Alzheimer's disease. Accordingly, the Korean success was greeted with scientific delight and a transfer (therapeutic cloning), they removed the flurry of accelerated research activity. In Canada, nucleus of a human egg cell and replaced it with a parliamentary committee voted to legalize the use of excess embryos for stem-cell research. Sweden announced that it would support the cloning of embryos for therapeutic purposes, the United Kingdom authorized a private firm to begin deriving embryonic stem cells, and Singapore forged ahead with plans to spend \$300 million on Biopolis, a cutting-edge

> In the United States, by contrast, recent policy has moved sharply in the opposite direction. Following an August 2001 announcement by President George W. Bush, federal funding for stem-cell research has been restricted to roughly 19 stem-cell lines - those created before the President's announcement from embryos donated after in vitro fertilization. No federal funds may be used to investigate other lines or to create new ones. Although



N ENGL J MED 351;3 WWW.NEJM.ORG JULY 15, 2004

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

SEPTEMBER 21, 2006

Intracoronary Injection of Mononuclear Bone Marrow Cells in Acute Myocardial Infarction

Ketil Lunde, M.D., Svein Solheim, M.D., Svend Aakhus, M.D., Ph.D., Harald Arnesen, M.D., Ph.D., Michael Abdelnoor, Ph.D., Torstein Egeland, M.D., Ph.D., Knut Endresen, M.D., Ph.D., Arnfinn Bebekk, M.D., Ph.D., Arild Mangschau, M.D., Ph.D., Jan G. Fjeld, M.D., Ph.D., Hans Jørgen Smith, M.D., Ph.D., Eli Taraldsrud, M.D., Haakon Kiil Grøgaard, M.D., Reidar Bjørnerheim, M.D., Ph.D., Magne Brekke, M.D., Carl Müller, M.D., Einar Hopp, M.D., Asgrimur Ragnarsson, M.D., Jan E. Brinchmann, M.D., Ph.D., and Kolbjørn Forfang, M.D., Ph.D.,*

ABSTRACT

SACEGROUND

Previous studies have shown improvement in left ventricular function after intra- from the Department; of Cardiology coronary injection of autologous cells derived from bone marrow (BMC) in the acute (K.L., S.A., K.E., A.R., K.F.), Nuclear Medicin phase of myocardial infarction. We designed a randomized, controlled trial to further investigate the effects of this treatment.

Parlents with acute ST-elevation invocardial infarction of the anterior wall treated with percuraneous coronary intervention were randomly assigned to the group that Chical Research (M.A.), Ulevál University underwent intracoronary injection of autologous mononuclear EMC or to the control Hospital and the institute for Experimental group, in which neither aspiration nor sham injection was performed. Left ventricular function was assessed with the use of electrocardiogram-gated single-photon-emission computed tomography (SPECT) and echocardiography at baseline and magnetic Cardiology, Wkshospitalet University resonance imaging (MRI) 2 to 3 weeks after the infarction. These procedures were repeated 6 months after the infarction. End points were changes in the left ventricular ejection fraction (IVEF), end-diastolic volume, and infarct size.

Of the 50 patients assigned to treatment with mononuclear BMC, 47 underwent intracoronary injection of the cells at a median of 6 days after myocardial infarction. There were 50 patients in the control group. The mean (4SD) change in LVEF, mea- N Engl j Med 2006;355:2199-209. sured with the use of SPECT, between baseline and 6 months after infarction for all Copyright to 2006 Minimum Medical Study patients was 7.6±10.4 percentage points. The effect of BMC treatment on the change in LVEF was an increase of 0.6 percentage point (95% confidence interval [CI], -3.4 to 4.6: P=0.77) on SPECT, an increase of 0.6 percentage point (95% CL -2.6 to 3.8: P=0.70) on echocardiography, and a decrease of 3.0 percentage points (95% Cl, 0.1 to -6.1; P=0.054) on MRI. The two groups did not differ significantly in changes in left ventricular end-diastolic volume or infarct size and had similar rates of adverse events.

With the methods used, we found no effects of intracoronary injection of autologous mononuclear BMC on global left ventricular function. (Clinical Trials gov number, NCT00199823.)

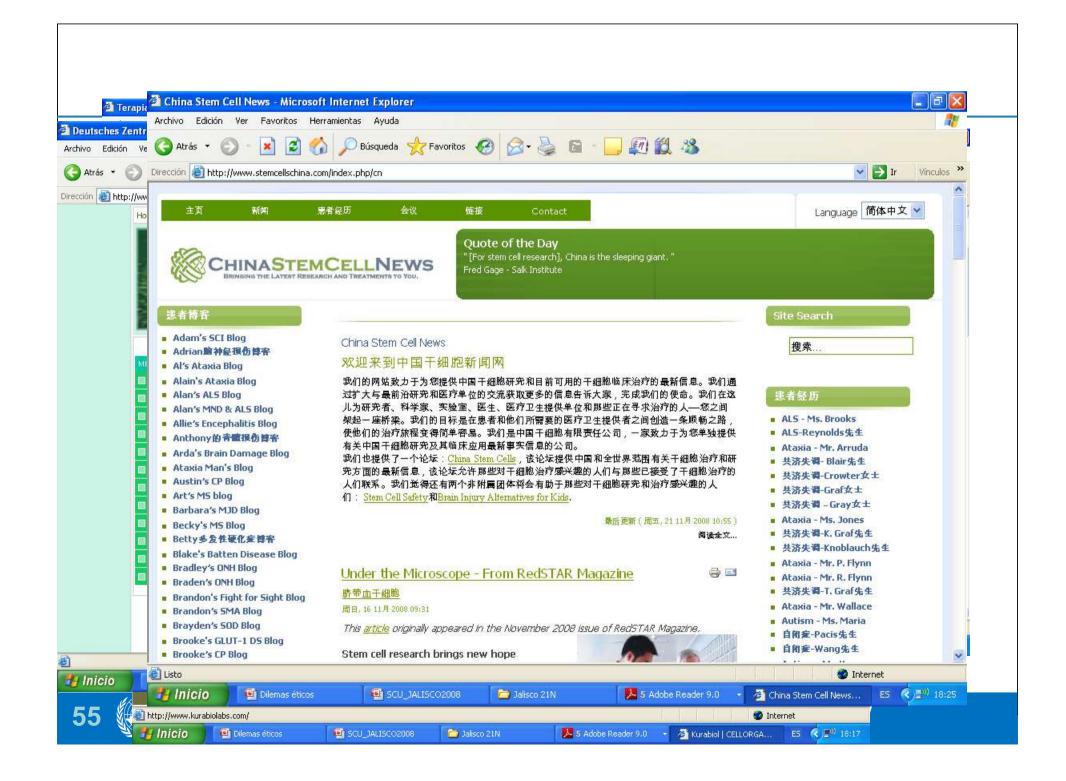
(J.G.F.), and Radiology (H.J.S., E.H.), and the Institute of Immunology (T.E., E.T., J.E.B.). Rikshospitalet University Hospital: the Departments of Cardiology (S.S., H.A., A.M., R.B.), Cardiovascular Radiology (M.B.), and Nuclear Medicine (C.M.), and the Unit of Epidemiology and Biostatistics, Center for Medical Research, University of Oslo IA.L. H.K.G.1 - all in Oslo. Address reprint requests to Dr. Lunde at the Department of Hospital, 0027 Oslo, Norway, or at ketil. underbrieshosnitalet no

*Members of the Steering Committee and the Data and Safety Monitoring Board of the Autologous Stem-Cell Transplantation in Acute Myocardial Infarction (ASTAMI) study are listed in the Appendix.



Internet is a powerful tool





Stem cell therapy for burns, not aging, says FDA





STEM cell therapy should only apply to skin grafting for burn patients and not for anti-aging purposes, according to the Food and Drug Administration (FDA).

"Up to now, there is no evidence that stem cell therapy has anti-aging effects," said FDA acting Director General Kenneth Hartigan-Go.

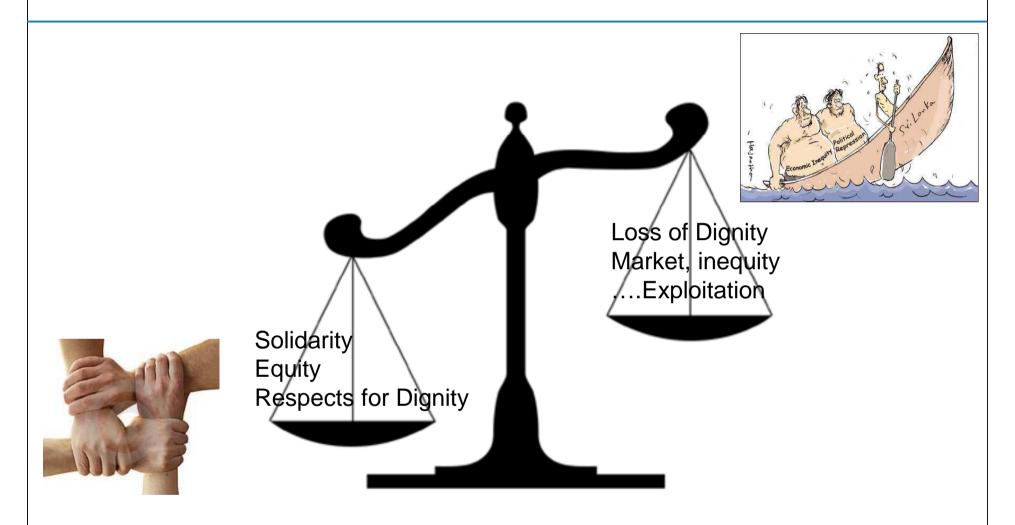
The FDA recognizes only hematopoietic (pertaining to the formation and development of blood cells) stem cell transplantation, corneal resurfacing with limbal stem cells and skin regeneration with epidermal stem cells "as generally accepted standards of health care."

Asked if this meant "anti-aging" stem cell therapies would not be allowed in the Philippines, Go said: "It means that if the health claim is for burn patients, requirements that need to be submitted—like clinical trial reports—are expected to be complete, whereas if the claim is for anti-aging, then the requirements may be more extensive and intensive considering that products for anti-aging claims are still controversial."

Facility accreditation

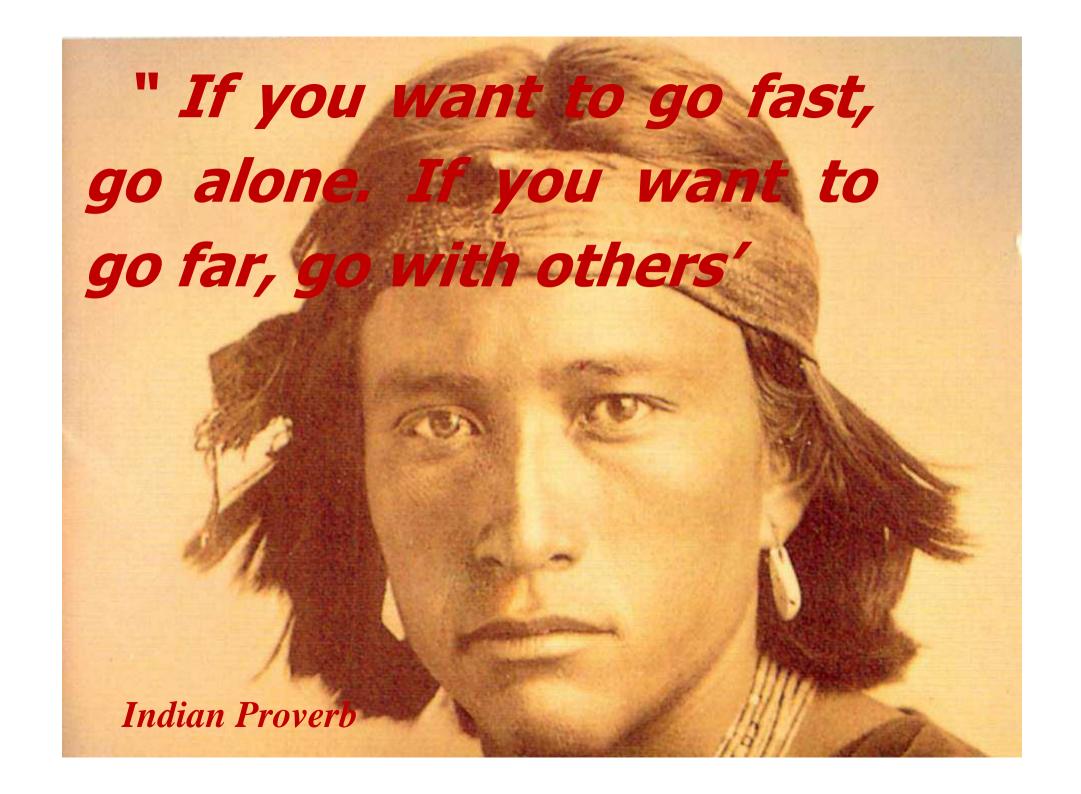


Transplantation Progresses on a unsteady scale



Role of Global and Regional Scientific and Professional Societies in the Global Governance of HSCT

- Developing and monitoring global codes of practice about ethical issues along the Guiding Principles
- Promoting global good practice in relation to quality and safety
- Advocating for globally harmonized practices such as accreditation and use of consistent information standards
- In collaboration with all stakeholders
 - Monitoring regional and global access
 - Monitoring outcome data
 - Contributing to vigilance and surveillance
 - And ensure transparency





Worldwide Network for Blood & Marrow Transplantation (WBMT)

Member Societies of WBMT



European Group for Blood and Marrow Transplantation (EBMT) www.ebmt.org



Center for International Blood and Marrow Transplant Research (CIBMTR)
www.cibmtr.org



Asia Pacific Blood and Marrow Transplantation Group www.apbmt.org



World Marrow Donor Association http://www.worldmarrow.org/



American Association of Blood Banks www.aabb.org



The Eastern Mediterranean Blood and Marrow Transplantation Group www.embmt.org



Netcord www.netcord.org



Eurocord WWW.8UI838IIB.8I





The Australasian Bone Marrow Transplant Recipient Registry http://www.abmtrr.org



Worldwide Network for Blood & Marrow Transplantation (WBMT)

Member Societies of WBMT



European Group for Blood and Marrow Transplantation (EBM! www.ebmt.org



Center for International Blood and Marrow Transplant Research



Asia Pacific Blood and Marrow Transplantation Group www.apbmt.org



World Marrow Donor Association



American Association of Blood Banks



www.aabb.org



The Eastern Mediterranean Blood and Marrow Transplantation www.embmt.org



Netcord www.netcord.org



Eurocord gra.brasarus.www



The Australasian Bone Marrow Transplant Recipient Registry http://www.abmtrr.org



The European School for Haematology



The European Federation for Immunogenetics









Joint Accreditation Committee-ISCT (Europe) www.jacie.org



Bone Marrow Donors Worldwide lgro.wbmd.www.lcqtttp://www.bmd.www



Foundation for the Accreditation of Cellular Therapy www.factwebsite.org



American Society for Blood and Marrow Transplantation www.asbmt.org



American Society for Histocompatibility and Immunogenetics http://www.ashi.hla.org/



European Marrow Donor Information System www.worldmarrow.org/index.php?id-286&type-1 www.emdis.net



International Society of Blood Transfusion http://www.isbtweb.org



American Society for Apheresis (ASFA) http://www.apheresis.org



Latin America Blood and Marrow Transplantation Group labmt@wbmt.org



International Cellular Therapy Coding and Labeling Advisory Group www.ICCBBA.org

