



**World Health
Organization**

WWW.WBMT.ORG

3rd & 4th October 2013



Legislative and **ethical** frameworks for Haematopoietic Stem Cell Donation & transplantation in Latin America



Ethics



Ethics

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



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.

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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

GP 3
Maximizing DD
Protecting LD

GP 6
Promoting
No advertising

GP 7
Reasonability
For transplant origin

GP 8
Justifiable fees

GP 2
Death
No conflict

GP 4
Protecting the
incompetent

GP 9
Equitable allocation

GP 1
Consent DD

Process

Donor

Recipient

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

GP 11 Transparency, openness to scrutiny, anonymity

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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.

GP 1
Consent DD



Donor

Process



Recipient

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

GP 2
Death
No conflict

GP 1
Consent DD

Process

Donor

Recipient

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

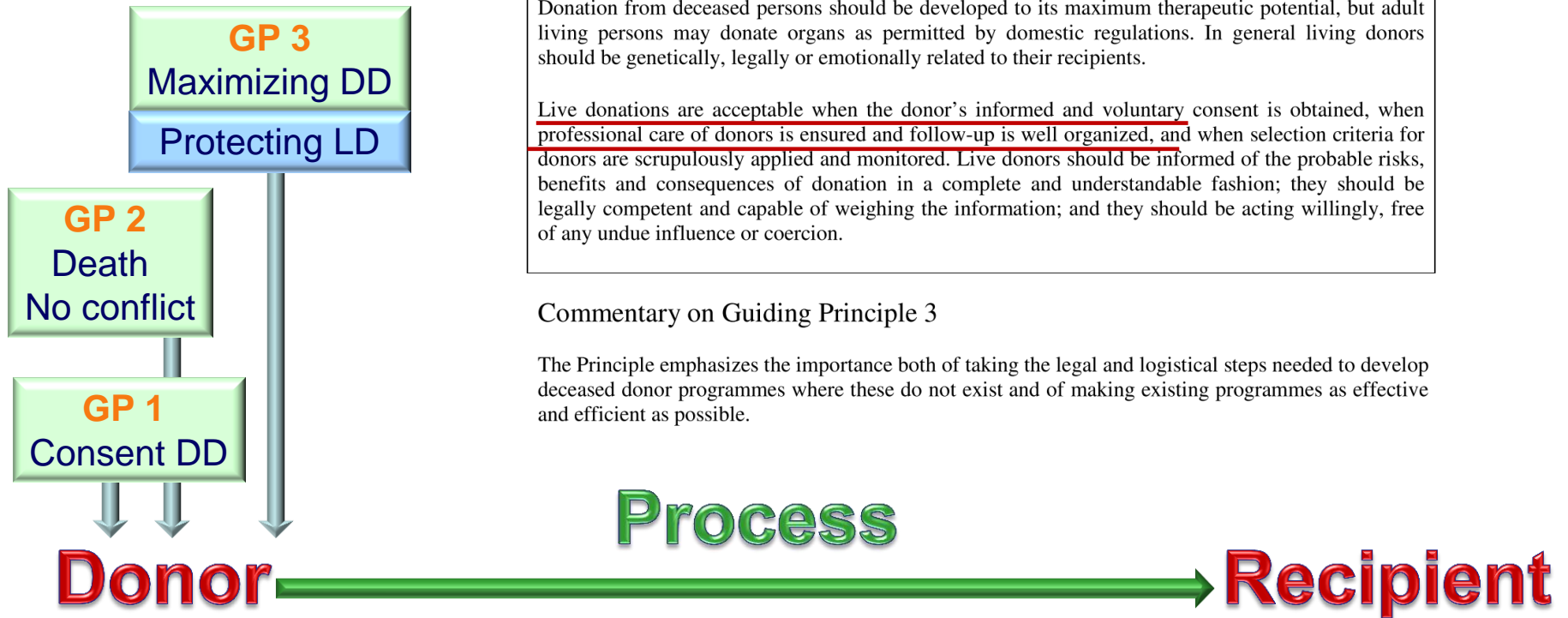
Guiding Principle 3

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.



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.



The Declaration of Istanbul



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.

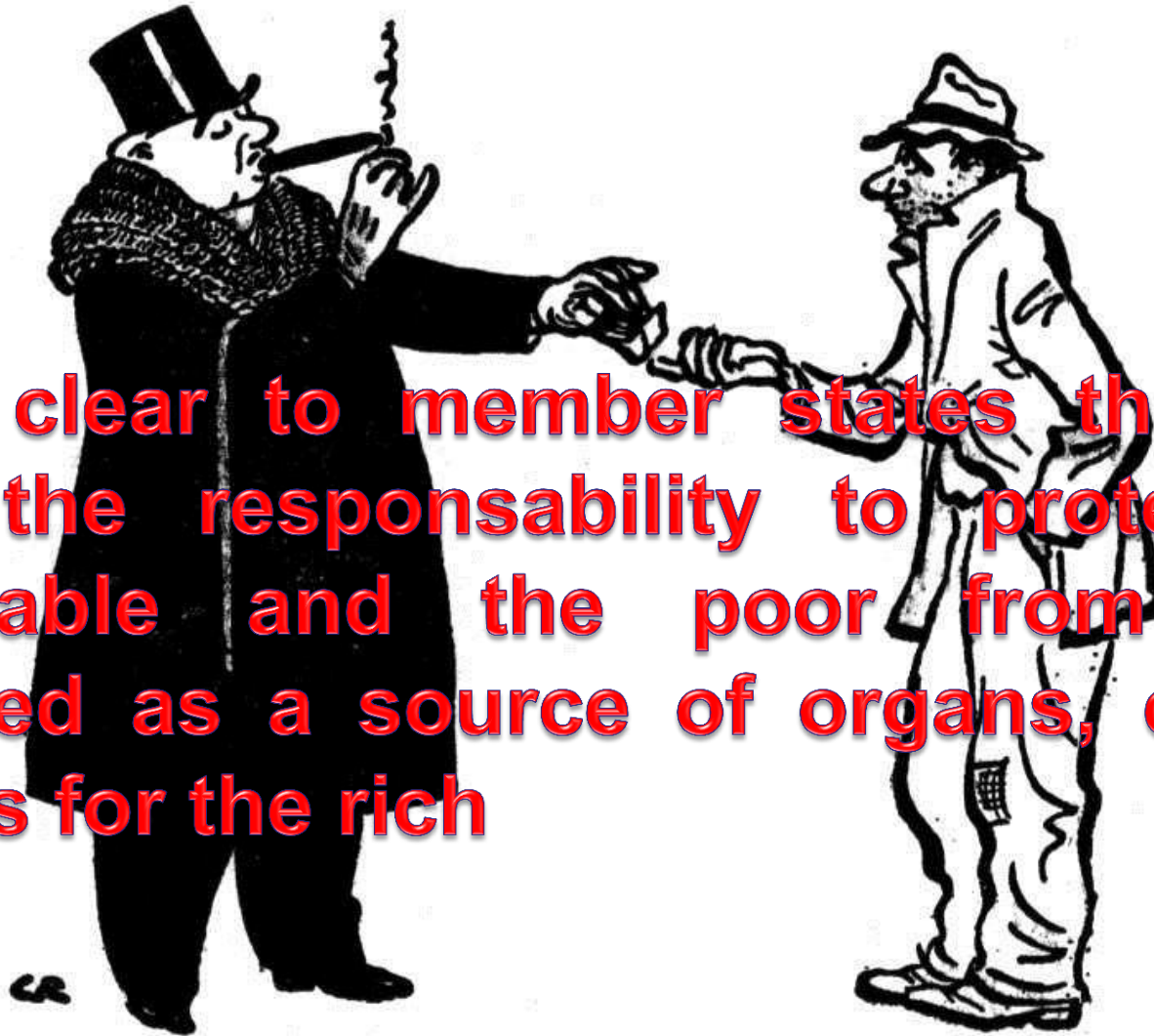
International Summit
Transplant Tourism
Organ Trafficking
Istanbul

International Summit
Transplant Tourism and
Organ Trafficking



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

Made clear to member states that they have the responsibility to protect the vulnerable and the poor from being exploited as a source of organs, cells or tissues for the rich



Transplant Tourism & Organ trafficking

Online Newspaper
June 20, 2013
San José, Costa Rica

tico  times. *net*

Home More news Business Sustainable Living Travel Arts & Leisure Opinion Weekend Region

NEWS BRIEFS

Costa Rican doctor arrested on suspicion of organ trafficking

Posted: Tuesday, June 18, 2013 - By Lindsay Fendt
Police have identified three patients who sold organs to the trafficking ring. One donor allegedly died after the operation.



Lindsay Fendt

Officials from the OIJ search Doctor Francisco José Mora outside his office at Calderón Guardia Hospital Tuesday morning. Courtesy of the OIJ

THE WALL STREET JOURNAL.

EUROPE EDITION Friday, March 23, 2012 As of 6:34 AM EDT

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TOP STORIES IN BUSINESS 1 of 12



Brazil's Batista Says He'll Rise Again



Siemens Heirs Ask for Calm



Funders of Lawsuits 7 Knocks

HEALTH INDUSTRY | March 23, 2012, 6:34 a.m. ET

China to Stop Harvesting Inmate Organs

Article

Comments (50)



By LAURIE BURKITT

BEIJING—China officials plan to phase out organ harvesting of death-row inmates, a move to overhaul a transplant system that has for years relied on prisoners and organ traffickers to serve those in need of transplants.

Article rank 16 Sep 2013 Kuwait Times By Nawara Fattahova

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

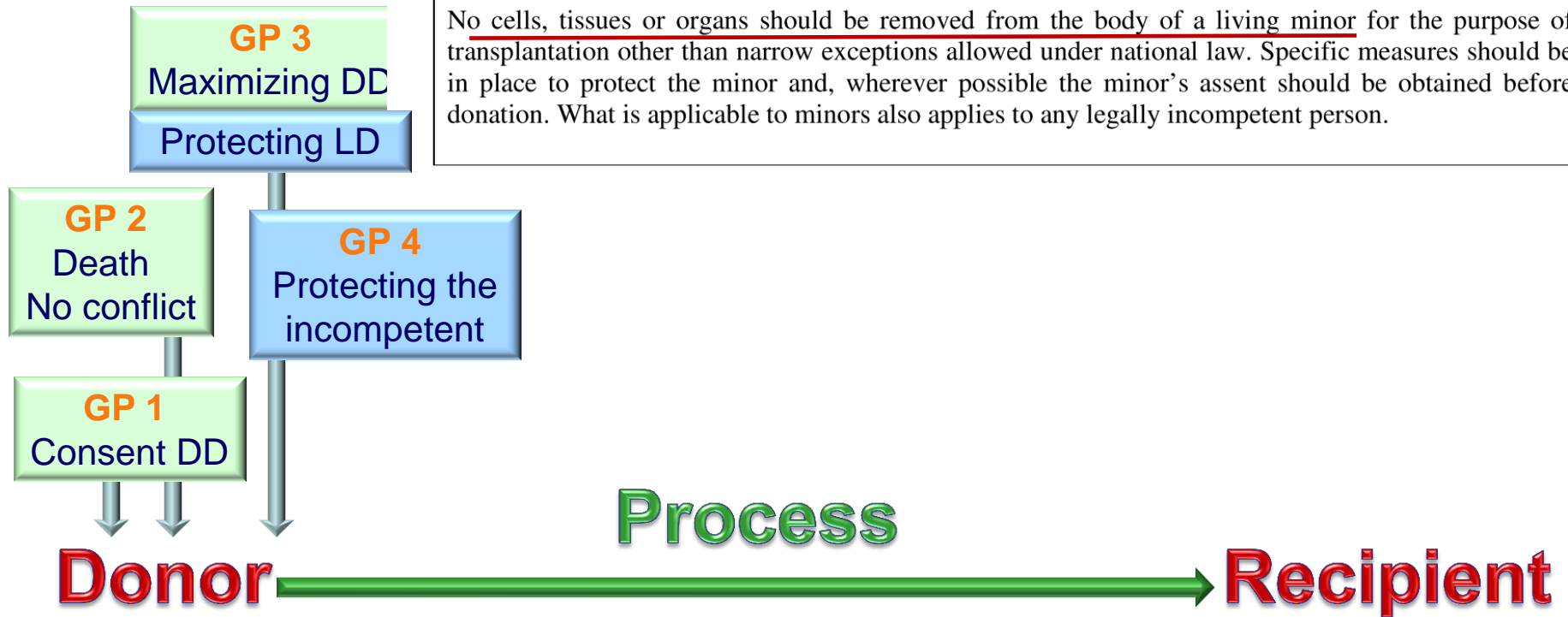
He added that KTS kidney transplants are performed in Kuwait, while liver transplants are subcontracted to specialists in Saudi Arabia. In each case, the donor's family receives compensation from the given country's Ministry of Health.

Reiterating his concerns regarding illegal organ

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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 narrow exceptions allowed under national law. 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.



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Donor

Recipient

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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.

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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

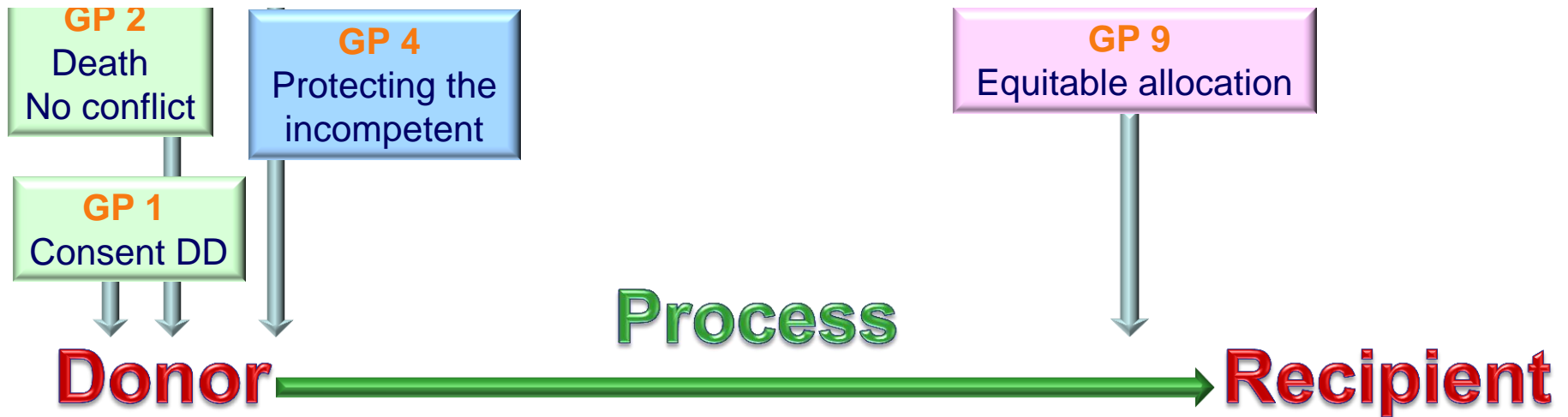
All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

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;

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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

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Transplant system will 'ensure fair allocation'

Updated: 2013-04-12 00:42
By Shan Juan (China Daily)

Print Mail Large Medium Small Share 0

Computer to prioritize patients according to their medical needs

The top health authority is set to issue a regulation ordering mandatory use of a computerized organ allocation system by hospitals in a bid to ensure transparent and fair allocation of organ donations, according to a senior official.

Huang Jiefu, former vice-minister of health, told China Daily in an exclusive interview that the regulation will enhance the efficiency of organ sharing and save more needy patients' lives.

Huang, head of the organ transplant committee of the National Health and Family Planning Commission, made the comments in response to concerns over fairness after reports said that only one-third of the nation's public organ donations had been allocated by the system.

"Organ allocation is in fact life allocation, and people won't donate without fair practices," he said.

Wang Haibo, director of the China Organ Transplant Response System Research Center at the University of Hong Kong, said the policy was developed after research based on dozens of countries' allocation policies and several discussions with Chinese experts and officials.

INSIGHT & OPINION
MON Sep 16, 2013 Updated: 8:37pm

110 SCMP South China Morning Post

Home News Business Comment Lifestyle Sport Property Ma

Home Comment Insight & Opinion Trending Xi Jinping Mo Yan Jack Ma

COMMENT • INSIGHT & OPINION • LEADER

China's computerised organ transplant system is step forward

SCMP Editorial Monday, 26 August, 2013, 4:04am

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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.

Global Observatory on Donation and Transplantation

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Networks

[RCIDT - Iberoamerican Council of Donation and Transplantation](#)

GLOBAL OBSERVATORY ON DONATION AND TRANSPLANTATION

GODT



Last global news

 Turkmenistan adopts regulations in organ transplantation field, August 2013

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation

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A nighttime photograph of the Fontana del Gallo in Bologna, Italy. The fountain is illuminated, showing a central figure holding a spear. The background features the historic architecture of the city, including a large building with arched windows and a crenellated wall. The text 'Bologna Initiative for Global Vigilance and Surveillance' is overlaid in white, serif font.

Bologna Initiative
for Global Vigilance and Surveillance

BIG V&S

- 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**

Objective: communicating vigilance information as widely as possible in the interests of improving the safety of MPHO worldwide

- ✓ **More than 900 documented case types** can be searched in a structured way by organ, tissue or cell type and/or incident type
 - associated bibliographic references and expert analyses.
- ✓ **Reactions**
 - Infectious transmissions of all types, malignancy transmissions, and genetic transmissions to transplant recipients and to the offspring of children born from donated gametes.
- ✓ **Events**
 - caused by process failures and reactions in living donors
- ✓ Site and search tools **publicly available** (without username and password)
- ✓ **Language specific interface in Regions.**

Latin America



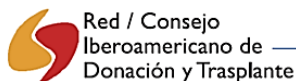


Red / Consejo Iberoamericano de Donación y Trasplante



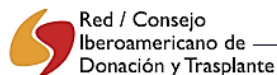
América Latina





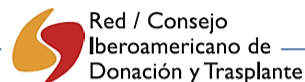
RESOLUCIÓN CD49.R18.
MARCO DE POLÍTICA PARA LA DONACIÓN
Y EL TRASPLANTE DE ORGANOS HUMANOS

Washington, D.C., EUA, del 28 de septiembre al 2 de octubre de 2009



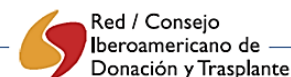
RECOMENDACIÓN REC-RCIDT-2008 (8)
CONSIDERACIONES BIOÉTICAS SOBRE LA DONACIÓN
Y EL TRASPLANTE DE ÓRGANOS, TEJIDOS Y CÉLULAS

RED/CONSEJO IBEROAMERICANO DE DONACIÓN Y TRASPLANTES



INTRODUCCIÓN

DECLARACIÓN DE QUITO SOBRE TERAPIAS
CELULARES SIN EVIDENCIA DEMOSTRADA



RECOMENDACIÓN REC-RCIDT-2009 (10)
SOBRE TERAPIA CELULAR

RED/CONSEJO IBEROAMERICANO DE DONACIÓN Y TRASPLANTES

Legislative framework



Legislative framework

- ✓ General aspects are included in all of them, but mainly related with organ transplantation
- ✓ HSC donation&transplantation normative only appear in Argentina, Brazil, Colombia, Ecuador, Paraguay and Peru
- ✓ Promotion of altruistic donation (according to GP 6) is only found in Brazil, Colombia, Ecuador, Panama and Venezuela.

Legislative framework



Principles and rights

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

Legislative framework

A satellite-style map of South America, showing the continent's geographical features and surrounding oceans. The map is dark, with green and brown tones representing land and vegetation. The text is overlaid on the map.

✓ Quality process

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 York Times
nytimes.com

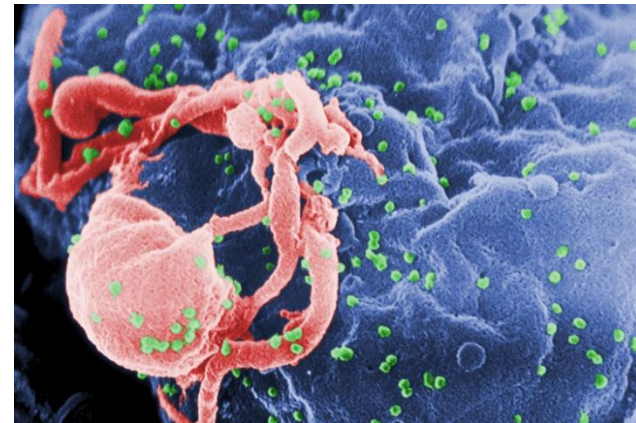
November 13, 2007

Four Transplant Recipients Contract H.I.V.

By [DENISE GRADY](#)

Four transplant recipients in Chicago have contracted [H.I.V.](#) from an organ donor, being spread by organ transplants.

The organs also gave all four patients [hepatitis C](#), in what health officials say was spread simultaneously by a transplant.



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.

For the first time in 15 years, there has been documented 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.

Among the questions raised are the following: Should potential recipients be informed about the general risks associated with transplantation or those specifically associated with an identified organ? Should the risks engendered by the behavior of donors be treated differently from those asso-

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

A well-known limitation of the safety of organ transplantation is that antibody-based tests to detect viruses have poor sensitivity within the first few weeks after infection.² Although more sensitive nucleic acid–amplification tests are now used in some regions, even these tests do not fully elim-

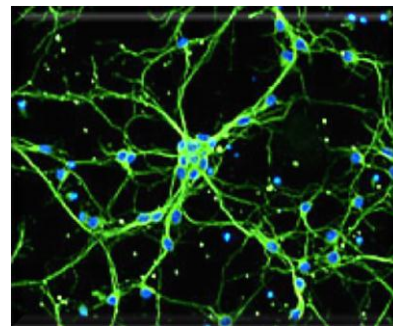
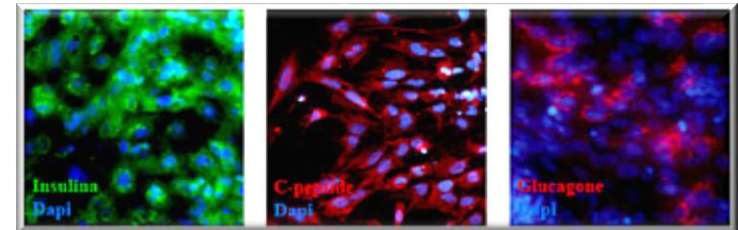


Legislative framework

A satellite-style map of South America is visible in the background, showing the continent's outline and some internal geographical features like rivers and terrain. The map is dark and serves as a background for the text.

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

STEM CELLS THERAPY



INTRODUCCIÓN

DECLARACIÓN DE QUITO SOBRE TERAPIAS CELULARES SIN EVIDENCIA DEMOSTRADA

PREÁMBULO

Los Estados Miembros que integran la Red/Consejo Iberoamericano de Donación y Trasplante (en adelante “RCIDT”), reunidos en Quito, Ecuador;

te de órganos, tejidos y células humanas;

— Conscientes del incremento alarmante en los últimos años de los fraudes existentes en el campo de la terapia celular sin evidencia científica demostrada, con el consecuente riesgo

no haya sido demostrada y que no garantice la seguridad en los pacientes;

II. La condena a la adquisición de partes del cuerpo humano para trasplante donde exista explotación de las poblaciones más vulnerables, y en donde

The Business of Stem Cells

Debora Spar, Ph.D.

On February 12, 2004, a team of Korean scientists made global headlines. Using somatic-cell nuclear transfer (therapeutic cloning), they removed the nucleus of a human egg cell and replaced it with 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 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

with Alzheimer's disease. Accordingly, the Korean success was greeted with scientific delight and a flurry of accelerated research activity. In Canada, 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 science park focused on stem-cell technology.

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



Stem Cell - Microsoft Internet Explorer

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Atrás Búsqueda Favoritos Ir Vínculos

Dirección http://www.bancostemcell.com/paginas/celulas/celulas_importancia.htm



Stem Cell
Banco de Células Madre

Viernes 21 de Noviembre de 2008

- Inicio
- Quiénes Somos
- Células Madre
- Sangre del Cordón
- Importancia de Crio-preservar
- Algunas Preguntas
- Enfermedades Tratables
- Kit Stem Cell
- Solicitud
- Zona de Descargas
- Contacto - Delegaciones
- Ver Video Informativo

Importancia de Crio-preservar

... una **oportunidad** única en la vida. Ahora o nunca !

Son muchas las ventajas de Crio-preservar, entre otras:

- No existe ningún tipo de problema, ni ético ni para la salud del bebé o de la madre. La extracción no interfiere en el cuidado y seguridad de la madre o el recién nacido.
- La recolección no afecta ni atenta contra la salud de otra persona.
- Actualmente se estudia la réplica y multiplicación de células madre.
- Las muestras se procesan y crioconservan en nuestros laboratorios de Alemania, al tanto de la última tecnología y normas GMP.
- Disponibilidad inmediata de la muestra extraída para su aplicación terapéutica.



Las muestras de sangre se preparan según las rigurosas normas de la Ley Alemana del Medicamento, siguiendo los protocolos de actuación denominados "Standard GMP". **GMP (Good Manufacturing Practice)**

Inicio Dilemas éticos SCU_JALISCO2008 Jalisco 21N Adobe Reader 9.0 Stem Cell - Microsoft ... ES 18:28

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

SEPTEMBER 21, 2006

VOL. 355 NO. 12

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 Ilebakk, 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

BACKGROUND

Previous studies have shown improvement in left ventricular function after intracoronary injection of autologous cells derived from bone marrow (BMC) in the acute phase of myocardial infarction. We designed a randomized, controlled trial to further investigate the effects of this treatment.

METHODS

Patients with acute ST-elevation myocardial infarction of the anterior wall treated with percutaneous coronary intervention were randomly assigned to the group that underwent intracoronary injection of autologous mononuclear BMC or to the control 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 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 (LVEF), end-diastolic volume, and infarct size.

RESULTS

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 (\pm SD) change in LVEF, measured with the use of SPECT, between baseline and 6 months after infarction for all 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% CI, -2.6 to 3.8 ; $P=0.70$) on echocardiography, and a decrease of 3.0 percentage points (95% CI, 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.

CONCLUSIONS

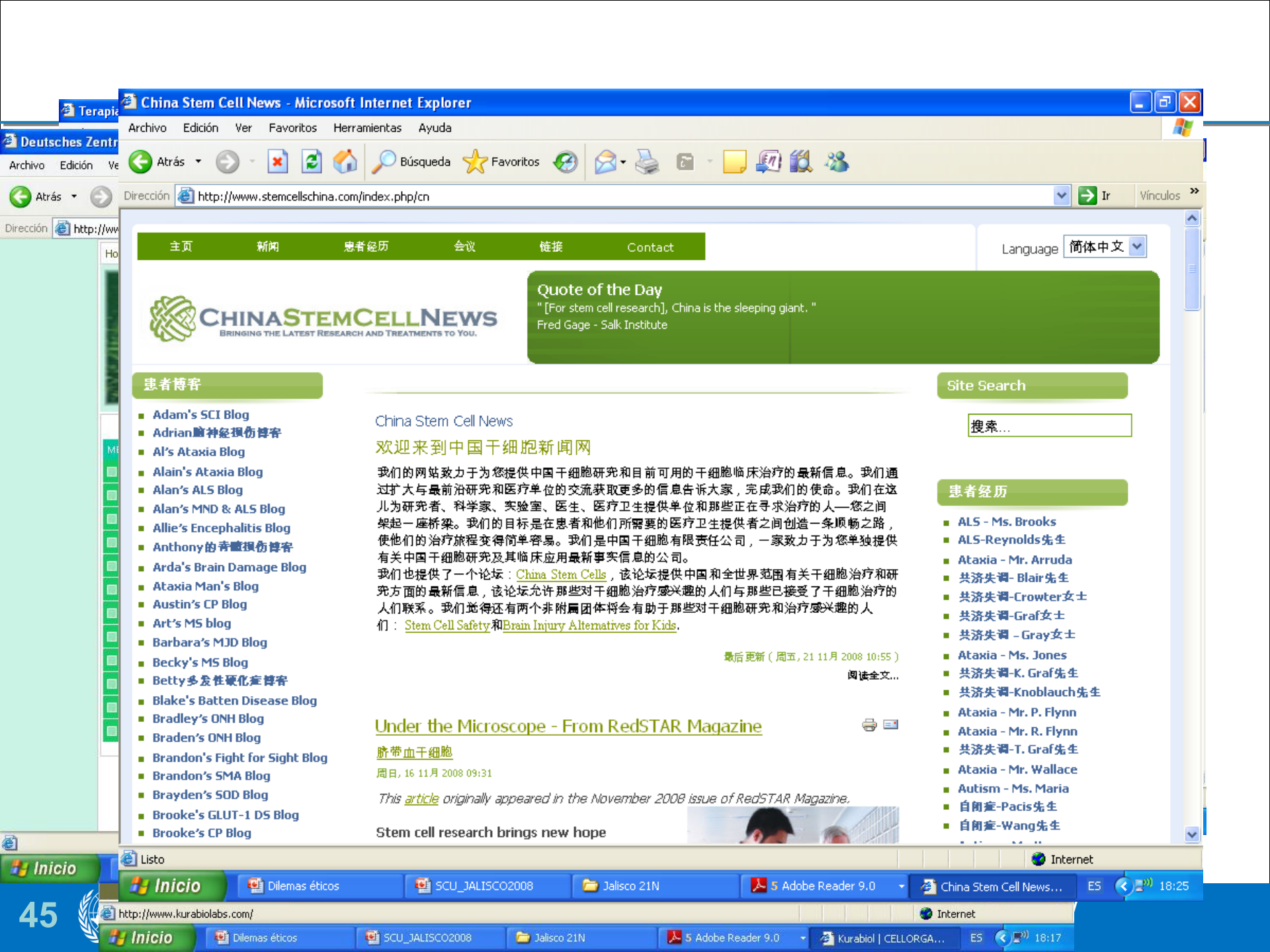
With the methods used, we found no effects of intracoronary injection of autologous mononuclear BMC on global left ventricular function. (ClinicalTrials.gov number, NCT00199823.)

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*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.

N Engl J Med 2006;355:1199-209.
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Quote of the Day
" [For stem cell research], China is the sleeping giant. "
Fred Gage - Salk Institute

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China Stem Cell News

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我们也提供了一个论坛：[China Stem Cells](#)，该论坛提供中国和全世界范围有关于细胞治疗和研究方面的最新信息，该论坛允许那些对干细胞治疗感兴趣的人们与那些已接受了干细胞治疗的人们联系。我们觉得还有两个非附属团体将会有助于那些对干细胞研究和治疗感兴趣的人们：[Stem Cell Safety](#)和[Brain Injury Alternatives for Kids](#)。

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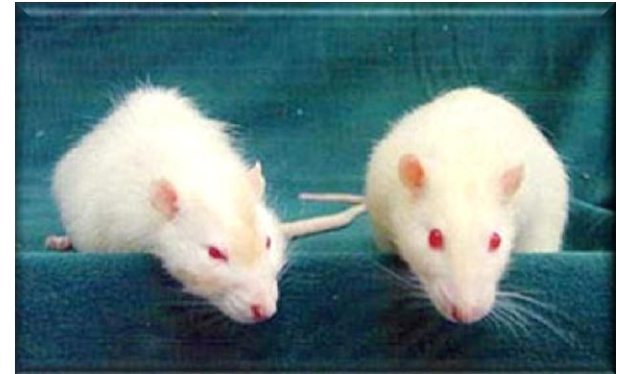
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This article originally appeared in the November 2008 issue of RedSTAR Magazine.

Stem cell research brings new hope





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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."

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