



**ABSTRACT
WHO GUIDING PRINCIPLES
ON HUMAN CELL, TISSUE AND ORGAN
TRANSPLANTATION**

Mexico City, 2010

Preamble

1. As the Director-General's report to the Executive Board at its Seventy-ninth session pointed out, human organ transplantation began with a series of experimental studies at the beginning of the twentieth century.
2. The shortage of available organs has not only prompted many countries to develop procedures and systems to increase supply but has also stimulated commercial traffic in human organs, particularly from living donors who are unrelated to recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades. Moreover, the growing ease of international communication and travel has led many patients to travel abroad to medical centers that advertise their ability to perform transplants and to supply donor organs for a single, inclusive charge.
3. Over the past 17 years the Guiding Principles have greatly influenced professional codes and practices as well as legislation around the world.
4. The following Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. The Guiding Principles do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents collected for transfusion purposes. Cells, tissues and organs may be removed from deceased and living persons for the purpose of transplantation, only in accordance with the following Guiding Principles.

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.

Guiding Principle 2

Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.

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.

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.

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.

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.

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.