

PART 1. DRAFT GUIDING PRINCIPLES ON HUMAN ORGAN TRANSPLANTATION

Introduction

1. In resolution WHA40.13, adopted in May 1987, the Fortieth World Health Assembly requested the Director-General "to study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants". 1 The response to this request was initiated in June 1989 following the adoption by the Forty-second World Health Assembly, in May 1989, of resolution WHA42.5 (Preventing the purchase and sale of human organs).

2. In order to take due account of the diversity in systems of health care and law, and of their social, cultural, religious and medical circumstances, the Director-General initiated a process of consultation involving a broad range of organizations and individual experts. 2 The principal initiatives were the establishment of an informal working group at WHO headquarters (with representatives from all relevant WHO programmes, as well as the Secretary-General of CIOMS) and the convening of an informal consultation on organ transplantation in Geneva (2-4 May 1990), 3 with international experts in organ transplantation, medical ethics, health policy and law, and representatives of intergovernmental and nongovernmental organizations.

3. The consultation expressed the view that it was "indeed feasible to develop the Guiding Principles that had been called for in resolution WHA40.13" and reviewed an initial draft of a set of Guiding Principles. On the basis of the outcome of the consultation as set forth in its report, the initial draft was amended and widely distributed for comment to all participants and to other experts on medical, legal, ethical, cultural, religious and health policy aspects of organ transplantation. It was also sent for comment to all the WHO regional offices. A second informal consultation, with smaller membership, was convened in Geneva on 3 and 4 October 1990, 4 in order to review the second draft of the Guiding Principles in the light of the comments and suggestions received, and to prepare a third draft from which the final draft is derived (see below).

4. The draft Guiding Principles are presented as a considered response to the 1987 and 1989 Health Assembly resolutions and as a link in a process that may lead to consideration by the Forty-fourth World Health Assembly of the adoption of Guiding Principles on Human Organ Transplantation, for recommendation to Member States under Article 23 of the Constitution.

GUIDING PRINCIPLES ON HUMAN ORGAN TRANSPLANTATION

PREAMBLE

1. As the Director-General's report to the seventy-ninth session of the Executive Board pointed out, human organ transplantation began with a series of experimental studies at the beginning of this century. That report drew attention to some of the major clinical and scientific advances in the field since Alexis Carrel was awarded the Nobel Prize in 1912 for his pioneering work. Surgical transplantation of human organs from deceased, as well as living, donors to sick and dying patients

began after the Second World War. Over the past 30 years, organ transplantation has become a worldwide practice and has saved many thousands of lives. It has also improved the quality of life of countless other persons. Continuous improvements in medical technology, particularly in relation to tissue "rejection", have brought about expansion of the practice and an increase in the demand for organs. A feature of organ transplantation since its commencement has been the shortage of available organs. Supply has never satisfied demand, and this has led to the continuous development in many countries of procedures and systems to increase supply. Rational argument can be made to the effect that shortage has led to the rise of commercial traffic in human organs, particularly from living donors who are unrelated to recipients. There is clear evidence of such traffic in recent years, and fears have arisen of the possibility of related traffic in human beings. Health Assembly resolutions WHA40.13 and WHA42.5 are an expression of international concern over these developments.

2. These Guiding Principles are intended to provide an orderly, ethical, and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes. The term "human organ" is understood to include organs and tissues but does not relate to human reproduction, and accordingly does not extend to reproductive tissues, namely ova, sperm, ovaries, testicles or embryos, nor is it intended to deal with blood or blood constituents for transfusion purposes. The Guiding Principles prohibit giving and receiving money, as well as any other commercial dealing in this field, but do not affect payment of expenditures incurred in organ recovery, preservation and supply. Of particular concern to WHO is the protection of minors and other vulnerable persons from coercion and improper inducement to donate organs.

Organs and tissues (referred to in this text as "organs") may be removed from the bodies of deceased and living persons for the purpose of transplantation only in accordance with the following Guiding Principles.

GUIDING PRINCIPLE 1

Organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

- (a) any consents required by law are obtained; and
- (b) there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person's lifetime.

GUIDING PRINCIPLE 2

Physicians determining that the death of a potential donor has occurred should not be directly involved in organ removal from the donor and subsequent transplantation procedures, or be responsible for the care of potential recipients of such organs.

GUIDING PRINCIPLE 3

Organs for transplantation should be removed preferably from the bodies of deceased persons. However, adult living persons may donate organs, but in general such donors should be genetically related to the recipients. Exceptions may be made in the case of transplantation of bone marrow and other acceptable regenerative tissues.

An organ may be removed from the body of an adult living donor for the purpose of transplantation if the donor gives free consent. The donor should be free of any undue influence and pressure and sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent.

GUIDING PRINCIPLE 4

No organ should be removed from the body of a living minor for the purpose of transplantation. Exceptions may be made under national law in the case of regenerative tissues.

GUIDING PRINCIPLE 5

The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited.

GUIDING PRINCIPLE 6

Advertising the need for or availability of organs, with a view to offering or seeking payment, should be prohibited.

GUIDING PRINCIPLE 7

It should be prohibited for physicians and other health professionals to engage in organ transplantation procedures if they have reason to believe that the organs concerned have been the subject of commercial transactions.

GUIDING PRINCIPLE 8

It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered.

GUIDING PRINCIPLE 9

In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations.

Commentaries on the Guiding Principles

Commentary on the Preamble (underlined text):

The purpose of this introductory proposition is to establish a comprehensive and exclusive system for the removal of organs from deceased and living donors for transplantation. As cadaver donation is best dealt with by national legislation, each jurisdiction will determine the definition of "deceased person" and criteria of death, as well as the means of implementing the Guiding Principles.

Commentary on Guiding Principle 1:

There are two systems dealing with the obtaining of organs from deceased persons. These are (1) the "opting in"/"contracting in" ("explicit consent") system of post mortem organ removal, in which deceased persons expressly state before death that they approve such removal, or an appropriate family member expresses approval when the deceased person left no statement or other evidence to the contrary, and (2) the "opting out"/"contracting out" ("presumed consent") system. This presumes that organs may be removed for transplantation from the bodies of deceased persons unless those persons when alive stated their objections, or perhaps others who were close to them stated at an appropriate time that the persons objected to their deceased bodies being so treated. In the case of both the "opting in" and "opting out" systems, any statements or other adequate indications of opposition by persons to posthumous organ removal from their bodies will prevent such removal.

When a deceased person leaves no evidence of opposition to removal, the "opting in" system normally requires consent of an appropriate family member for organ removal. In the "opting out" system, no consent is required, but family members may take initiatives to state the opposition of the deceased person or of themselves.

Commentary on Guiding Principle 2:

This provision is designed to reduce the possibility of a conflict of interest that would arise if the physician or physicians determining the death of a potential donor were also involved in organ removal or implantation.

Commentary on Guiding Principle 3:

The first paragraph of this Principle is intended to emphasize the importance of developing cadaveric donation programmes in countries where this is culturally acceptable, and to discourage donations from living, genetically unrelated donors, except for transplantation of bone marrow and of other acceptable regenerative tissues.

The second paragraph seeks to protect potential donors from undue pressure and undue inducements from others. It emphasizes the necessity for complete and objective information to be given to the donor. It also takes into account issues relating to persons (other than minors) who are legally incompetent to fulfil the requirements for "free consent" or the other conditions specified in this paragraph.

Commentary on Guiding Principle 4:

This Principle provides for absolute prohibition of the removal of organs for transplantation from legal minors. However, an exception concerning regenerative tissues may be allowed by national legislation. In such cases, the protection of minors could be assured by requiring, among other

conditions, the minor's comprehending consent and the consent of the parent(s) or the legal guardian. The parent(s) or the legal guardian may have a conflict of interest, for example if they are responsible for the welfare of an intended recipient of the donated tissues. In such a case, prior permission of an independent body, such as a court or other appropriate authority of comparable independence or status should be required. However, an objection by the minor should take effect and prevail over any other consent.

Commentary on Guiding Principle 5:

This Principle is designed to prohibit traffic in human organs for payment. The method of prohibition, including sanctions, will be determined independently by each jurisdiction. The Principle does not prohibit payment of reasonable expenses incurred in donation, recovery, preservation and supply of organs for transplantation.

Commentary on Guiding Principle 6:

The intention of this Principle is to prohibit advertisements that have a commercial (profit-making) purpose. Promotion and encouragement of altruistic donation of human organs and tissues by means of advertisement or public appeal are not affected by this Principle.

Commentary on Guiding Principle 7:

This provision deals with the involvement of physicians and other health professionals in removal, intermediate management and implantation of organs with knowledge, actual or constructive, that commercial transactions have occurred.

Commentary on Guiding Principle 8:

This provision reinforces Guiding Principle 7 by restricting entrepreneurial practice in organ recovery and implantation. A medical or other health practitioner uncertain whether a fee proposed to be charged is justifiable may seek the opinion of an appropriate licensing or disciplinary authority before the fee is proposed or levied.

Commentary on Guiding Principle 9:

This provision is self-explanatory.