

ARCHIVED: WMA STATEMENT ON HUMAN ORGAN DONATION AND TRANSPLANTATION

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A. INTRODUCTION

1. Advances in medical sciences, especially surgical techniques, tissue typing and immuno-suppressive drugs, have made possible a significant increase in the rates of successful transplantation of organs. In the light of these developments, there is a need for renewed reflection on ethical issues concerning organ donation and transplantation and on principles relevant to the resolution of these issues. Therefore, the World Medical Association has undertaken a review of issues and principles concerning transplantation and has developed this policy to provide guidance to medical associations, physicians and other health care providers as well as to those who develop policy and protocols bearing on these issues.
2. This policy is based on principles of general and medical ethics. In matters of ethics, conflicts of values and principles are unavoidable; for example, there is a tension between a desire to procure organs for the purpose of providing important medical treatments on the one hand and the preservation of choice and personal liberty on the other. Applicable principles are referenced throughout this policy where they may help to clarify and make explicit the reasoning behind a given statement.

B. PROFESSIONAL OBLIGATIONS OF PHYSICIANS

1. The primary obligation of physicians is to their individual patients, whether they are potential donors or recipients of transplanted organs. In conjunction with this obligation physicians may also have responsibilities to the family members and close friends of their patients, for example, to seek and consider their views on organ retrieval from their deceased relative or friend. The obligation to the patient has primacy over any obligations that may exist in relationship to family members. Nevertheless, this obligation is not absolute; for example, the physician's responsibility for the well-being of a patient who needs a transplant does not justify unethical or illegal procurement of organs.
2. Physicians have responsibilities to society, which include promoting the fair use of resources, preventing harm and promoting health benefit for all; this may include promoting donation of organs.
3. Transplant surgeons should attempt to ensure that the organs they transplant have been obtained in accordance with the provisions of this policy and shall refrain from transplanting organs that they know or suspect have not been procured in a legal and ethical manner.

C. ORGAN PROCUREMENT: SOCIAL ASPECTS

1. The WMA encourages its members to support the development of comprehensive, coordinated national strategies concerning organ procurement in consultation and cooperation with all relevant stakeholders. In developing strategy, due consideration should be given to human rights, ethical principles and medical ethics. Ethical, cultural and societal issues arising in connection with such a strategy, and with the subject of donation and transplantation in general, should be resolved, wherever possible, in an open process involving public dialogue and debate informed by sound evidence.
2. Some types of organ transplantation have become established and important health care services. To the extent that the lack of organs is a barrier to the provision of needed treatment, the medical profession has an obligation to promote policies and protocols to procure organs for needed treatment consistent with societal values.
3. It is important that individuals become aware of the option of donation and have the opportunity to choose whether or not to donate (e.g. facilitated choice). Awareness and choice should be facilitated in a

coordinated multi-faceted approach by a variety of stakeholders and means, including media awareness and public campaigns. Physicians should provide their patients with the opportunity to make a choice with respect to organ donation, ideally in the context of an ongoing relationship with the patient and in advance of any crisis giving urgency to the choice.

4. The WMA supports informed donor choice. National Medical Associations in countries that have adopted or are considering a policy of “presumed consent”, whereby there is a presumption that consent has been given unless there is evidence to the contrary, or “mandated choice”, whereby all persons would be required to declare whether they wish to donate, should make every effort to ensure that these policies do not diminish informed donor choice, including the patient's right to refuse to donate.
5. Consideration should be given to the establishment of national donor registries to collect and maintain a list of country citizens who have chosen either to donate or not to donate their organs. Any such registry must protect individual privacy and the individual's ability to control the collection, use, disclosure of and access to his or her health information for purposes other than registration. Provisions must be in place to ensure that the decision is adequately informed and that registrants can withdraw from the registry without penalty.

D. ORGAN PROCUREMENT AT THE INSTITUTIONAL AND INDIVIDUAL LEVELS

1. Organ donation can be enhanced by local policies and protocols. The WMA recommends that organ procurement programmes, hospitals and other institutions in which procurement occurs should:
 - a. Develop policies and protocols encouraging the procurement of organs consistent with the statements in this policy. Such policies should be consistent with physicians' professional obligations and societal values, including free and informed decision making, privacy, and equitable access to needed medical care.
 - b. Make these policies and protocols known to transplant coordinators, physicians and other health care providers in the institution.
 - c. Ensure that adequate resources are available to support proper implementation of the policies and protocols.

E. DONATION AFTER DEATH

1. Physicians have an obligation to ensure that interactions at the bedside, including those discussions related to organ donation, are sensitive and consistent with ethical principles and with their fiduciary obligations to their patients. This is particularly so given that conditions at the bedside of dying patients are not ideal for the process of free and informed decision making. Protocols should specify that whoever approaches the patient, family members or other designated decision maker about the donation of organs should possess the appropriate combination of knowledge, skill and sensitivity for engaging in such discussions. Medical students and practising physicians should seek the necessary training for this task, and the appropriate authorities should provide the resources necessary to secure that training. It is mandatory that the person who approaches the patient or family about the donation decision not be a member of the transplant team.

F. FREE AND INFORMED DECISION MAKING ABOUT ORGAN DONATION

1. The WMA considers that the potential donor's wishes are paramount. In the event that the potential donor's wishes about donation are unknown and the potential donor has died without expressing a clear wish about donation, the family or a specified other person may serve as a substitute decision-maker and may be entitled to give or refuse permission for donation unless there are previously expressed wishes to the contrary.
2. Evidence of the free and informed decision of the potential donor, or, where legally relevant, of the appropriate substitute decision-maker, must be ascertained before organ procurement can begin. In countries where presumed consent is the legal norm, the organ procurement process should include reasonable steps to discover whether the potential donor has opted out of donation.

3. Success in procuring organs for transplant should not be construed as a criterion for measuring the quality of the process of free and informed decision-making. The quality of this process depends on whether the choice was adequately informed and free of coercion and not on whether the outcome is a decision to donate.
4. Free and informed decision making is a process requiring the exchange and understanding of information and the absence of coercion. Because prisoners and other individuals in custody are not in a position to give consent freely and can be subject to coercion, their organs must not be used for transplantation except for members of their immediate family.
5. In order for the choice to donate organs to be duly informed, prospective donors or their substitute decision makers should, if they desire, be provided with meaningful and relevant information. Normally, this will include information about:
 - a. in the case of living donors, the benefits and risks of transplantation,
 - b. in the case of deceased donors, procedures and definitions involved in the determination of death,
 - c. testing of organs to determine their suitability for transplantation, which may reveal unsuspected health risks in the prospective donors and their families,
 - d. in the case of deceased donors measures that may be required to preserve organ function until death is determined and transplantation can occur,
 - e. in the case of deceased donors what will happen to the body once death has been declared,
 - f. what organs they are agreeing to donate,
 - g. the protocol that will be followed concerning the family in the event that the family objects to donation, and
 - h. in the case of living donors, the implications of living without the donated organ.
6. Prospective donors should be informed that families sometimes object to donation; donors should be encouraged to discuss their choice with their family to prevent conflict.
7. Prospective donors or their substitute decision makers should be given the opportunity to ask questions about donation and should have their questions answered sensitively and intelligibly.
8. Where the wishes of the patient are known and there is no reason to believe that the choice to donate has been coerced, has not been adequately informed, or has changed, these wishes should be carried out. This should be clarified in law, policy and protocols. Under these circumstances, families should be encouraged to respect the patient's clearly expressed wishes.
9. Where the wishes of the patient are unknown or there is uncertainty about the patient's wishes, national law should prevail.
10. Protocols for free and informed decision making should also be followed in the case of recipients of organs. Normally, this should include information about:
 - a. the risks of the procedure,
 - b. the likely short, medium and long-term survival, morbidity, and quality-of-life prospects,
 - c. alternatives to transplantation, and
 - d. how organs are obtained.
11. In the case of living donors, special efforts should be made to ensure that the choice about donation is free of coercion. Financial incentives for providing or obtaining organs for transplantation can be coercive and should be prohibited. Individuals who are incapable of making informed decisions, for example minors or mentally incompetent persons, should not be considered as potential living donors except in extraordinary

circumstances and in accordance with ethics committee review or established protocols. In order to avoid a conflict of interest, the physician who obtains informed consent from the living donor should not be part of the transplant team for the recipient.

G. DETERMINATION OF DEATH

1. The WMA considers that the determination of death is a clinical matter that should be made according to widely accepted guidelines established by expert medical groups, and as outlined in The World Medical Association's Declaration of Sydney on the Determination of Death and the Recovery of Organs.
2. Protocols and procedures should be developed to educate patients and families about procedures for diagnosing death and the opportunities for donation after death.
3. In order to avoid a conflict of interest, the physician who determines and/or certifies the death of a potential organ donor should not be involved in the organ removal or in subsequent transplantation procedures or responsible for the care of potential recipients of these organs.

H. JUSTICE IN ACCESS TO ORGANS

1. The WMA considers there should be explicit policies open to public scrutiny governing all aspects of organ donation and transplantation, including the management of waiting lists for organs to ensure fair and appropriate access.
2. Policies governing the management of waiting lists should ensure efficiency and fairness. Criteria that should be considered in allocating organs include severity of medical need, length of time on the waiting list, and medical probability of success measured by such factors as type of disease, other complications, and histocompatibility. There should be no discrimination based on social status, lifestyle or behaviour.
3. Special appeals for organs for a specific recipient require further study and ethical examination to evaluate the potential impact on the fairness of allocation.
4. Payment for organs for donation and transplantation must be prohibited. A financial incentive compromises the voluntariness of the choice and the altruistic basis for organ donation. Furthermore, access to needed medical treatment based on ability to pay is inconsistent with the principles of justice. Organs suspected to have been obtained through commercial transaction must not be accepted for transplantation. In addition, the advertisement of organs in exchange for money should be prohibited. However, reasonable reimbursement of expenses such as those incurred in procurement, transport, processing, preservation, and implantation is permissible.
5. Physicians who are asked to transplant an organ that has been obtained through a commercial transaction should refuse to do so and should explain to the patient why such a medical act would be unethical: because the person who provided the organ risked his or her future health for financial rather than altruistic motives, and because such transactions are contrary to the principle of justice in the allocation of organs for transplantation.

I. EXPERIMENTAL AND NEWLY DEVELOPING TRANSPLANTATION PROCEDURES

1. The WMA considers that, although many transplantation procedures have become standard medical care for a range of medical conditions, others are experimental and/or morally controversial and require further research, safeguards, guidelines, and public debate.
2. Experimental procedures require protocols, including ethics review, that are different and more rigorous than those for standard medical procedures.
3. Xenotransplantation raises special issues, particularly in light of the risk of unwitting cross-species transmission of viruses and other pathogens. There is an urgent need for extensive public debate about xenotransplantation to ensure that developments in this field are consistent with societal values. International guidelines to govern these practices should be developed.
4. Transplantation of organs developed using cell nuclear replacement technologies requires scientific review,

public debate and appropriate guidelines before becoming accepted.