

WMA STATEMENT ON ORGAN AND TISSUE DONATION

*Adopted by the 63rd WMA General Assembly, Bangkok, Thailand, October 2012
and revised by the 68th WMA General Assembly, Chicago, United States, October 2017*

PREAMBLE

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 human organs and tissue. Yet, in all countries, a shortage of organ donors results in potentially avoidable loss of life. National medical associations should support attempts to maximise the number of donor organs available in their countries and to ensure that the highest ethical standards are maintained. The World Medical Association has developed this policy to assist medical associations, physicians, other health care providers and policy makers to achieve this.

This policy is based on a number of core ethical principles: altruism, autonomy, beneficence, equity and justice. These principles should guide those developing national policies and those operating within it, both in relation to organ procurement and to the distribution and transplantation of donor organs. All systems and processes should be transparent and open to scrutiny.

This statement applies to organ and tissue donation from both deceased and living donors. It does not apply to blood donation.

RAISING PUBLIC AWARENESS

2. It is important that individuals are aware of the option of donation and have the opportunity to choose whether or not to donate organs and/or tissue before and after their death. 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. In designing such campaigns account needs to be taken of any religious or cultural sensitivities of the target audience.

3. Through awareness raising campaigns, individuals should be informed of the benefits of transplantation, the impact on the lives of those who are waiting for a transplant and the shortage of donors available. They should be encouraged to think about their own wishes about donation, to discuss their wishes with their family and friends and to use established mechanisms to formally record them by opting into, or out of, donation.

4. The WMA advocates informed donor choice. National medical associations in countries that have adopted or are considering a policy of "presumed consent" (or opt-out), in which there is an assumption that the individual wishes to donate unless there is evidence to the contrary, or "mandated choice", in which all persons would be required to declare whether they wish to donate, should make every effort to ensure that these policies have been adequately publicised and do not diminish informed donor choice, including the patient's right not to donate.

5. Consideration should be given to the establishment of national donor registries to collect and maintain a list of citizens who have chosen either to donate or not to donate their organs and/or tissue. 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 other purposes. Provisions must be in place to ensure that the decision to sign up to a register is adequately informed and that registrants can withdraw from the registry easily and quickly and without prejudice.

6. Living organ donation is becoming an increasingly important component of transplantation programmes in

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many countries. Most living donation is between related or emotionally close individuals and small but increasing numbers are donating to people they do not know. Given that there are health risks associated with living organ donation, proper controls and safeguards are essential. Information aimed at informing people about the possibility of donating organs as a living donor should be carefully designed so as not to put pressure on them to donate and to minimise the risk of financial or other coercion. Potential donors should know where to obtain detailed information about what is involved, should be informed of the inherent risks and should know that there are safeguards in place to protect those offering to donate.

PROTOCOLS FOR ORGAN AND TISSUE DONATION FROM DECEASED DONORS

7. The WMA encourages its members to support the development of comprehensive, coordinated national protocols for deceased (also referred to as cadaveric) organ and tissue procurement in consultation and cooperation with all relevant stakeholders. Ethical, cultural and societal issues arising in connection with donation and transplantation should be resolved, wherever possible, in an open process involving public debate informed by sound evidence.

8. National and local protocols should provide detailed information about the identification, referral and management of potential donors as well as communication with those close to people who have died. They should encourage the procurement of organs and tissues consistent with this statement. Protocols should uphold the following key principles:

- Decisions to withhold or withdraw life-prolonging treatment should be based on an assessment of whether the treatment is able to benefit the patient. Such decisions must be, and must be seen to be, completely separate from any decisions about donation.
- The diagnosis of death should be made according to national guidelines and as outlined in the WMA's Declaration of Sydney on the Determination of Death and Recovery of Organs.
- There should be a clear separation between the treating team and the transplant team. In particular, the physician who declares or certifies the death of a potential donor should not be involved in the transplantation procedure. Nor should he/she be responsible for the care of the organ recipient.
- Countries that carry out donation following circulatory/cardiac death should have specific and detailed protocols for this practice.
- Where an individual has expressed a clear and voluntary wish to donate organs and/or tissue after death, steps should be taken to facilitate that wish wherever possible. This is part of the treating team's responsibility to the dying patient.
- The WMA considers that the potential donor's wishes are paramount. Relatives and those close to the patient should be strongly encouraged to support a deceased person's previously expressed wish to donate organs and/or tissues. Whenever possible, these conversations should occur prior to the death of the patient.
- Those charged with approaching the patient, family members or other designated decision maker about organ and tissue donation 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.
- Donation must be unconditional. In exceptional cases, requests by potential donors, or their substitute decision makers, for the organ or tissue to be given to a particular recipient may be considered if permitted by national law. Donors seeking to apply conditions that could be seen as discriminatory against certain groups, however, should be declined.

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9. Hospitals and other institutions where donation occurs should ensure that donation protocols are publicised amongst those likely to use them and that adequate resources are available for their implementation. They should also foster a pro-donation culture within the institution in which consideration of donation is the norm, rather than the exception, when a patient dies.

10. The role of transplant coordination is critical to organ donation. Those performing coordination act as the key point of contact between the bereaved family and the donation team and usually also undertake the complex logistical arrangements to make donation happen. Their role must be recognised and supported.

11. Deceased organ donation must be based on the notion of a gift, freely and voluntarily given. It should involve the voluntary and unpressured consent of the individual provided before death (by opting in or opting out of donation depending upon the jurisdiction) or the voluntary authorisation of those close to the deceased patient if that person's wishes are unknown. The WMA is strongly opposed to the commercialisation of donation and transplantation.

12. Prospective donors or their substitute health care decision makers should have access to accurate and relevant information, including through their general practitioners. Normally, this will include information about:

- The procedures and definitions involved in the determination of death,
- The testing that is undertaken to determine the suitability of the organs and/or tissue for transplantation and that this may reveal previously unsuspected health risks in prospective donors and their families,
- Measures that may be required to preserve organ function until death is determined and transplantation can occur,
- What will happen to the body once death has been declared,
- What organs and tissues can be donated,
- The protocol that will be followed in the event that the family objects to donation, and
- The possibility and the process of withdrawing consent.

13. Prospective donors or their substitute health care decision makers should be given the opportunity to ask questions about donation and should have their questions answered sensitively and intelligibly.

14. Where both organs and tissues are to be donated, information should be provided, and consent obtained, for both together in order to minimise distress and disruption to those close to the deceased.

15. In some parts of the world a contribution towards funeral costs is given to the family of those who donate. This can be viewed either as appropriate recognition of their altruistic act or as a payment that compromises the voluntariness of the choice and the altruistic basis for donation. The interpretation may depend, in part, on the way it is set up and managed. When considering the introduction of such a system, care needs to be taken to ensure that the core principles of altruism, autonomy, beneficence, equity and justice are met.

16. Free and informed decision making requires not only the provision of information but also the absence of coercion. Any concerns about pressure or coercion must be resolved before the decision to donate organs or tissue is made.

17. Prisoners and other people who are effectively detained in institutions should be eligible to donate after death where checks have been made to ensure that donation is in line with the individual's prior, un-coerced wishes and, where the individual is incapable of giving consent, authorisation has been provided by a family member or other authorized decision-maker. Such authorisation may not override advance withholding or refusal of consent.

18. Their death is from natural causes and this is verifiable.

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19. In jurisdictions where the death penalty is practised, executed prisoners must not be considered as organ and/or tissue donors. While there may be individual cases where prisoners are acting voluntarily and free from pressure, it is impossible to put in place adequate safeguards to protect against coercion in all cases.

ALLOCATION OF ORGANS FROM DECEASED DONORS

20. The WMA considers there should be explicit policies, open to public scrutiny, governing all aspects of organ and tissue donation and transplantation, including the management of waiting lists for organs to ensure fair and appropriate access.

21. Policies governing the management of waiting lists should ensure efficiency and fairness. Criteria that should be considered in allocating organs or tissue include:

- Severity and urgency of medical need,
- Length of time on the waiting list,
- Medical probability of success measured by such factors as age, type of disease, likely improvements in quality of life, other complications, and histocompatibility.

22. There must be no discrimination based on social status, lifestyle or behaviour. Non-medical criteria must not be considered.

PROTOCOLS FOR ORGAN AND TISSUE DONATION FROM LIVING DONORS

23. Living donation is becoming increasingly common as a way to overcome the shortage of organs from deceased donors. In most cases donors provide organs to relatives or people to whom they are emotionally close. A small number of individuals choose to donate an organ altruistically to a stranger. Another scenario is where one or more donor and recipient pairs are incompatible with each other but donate in the form of a cross-over or pooled donation system (for example, donor A donates to recipient B, donor B donates to recipient C and donor C donates to recipient A).

24. All potential donors should be given accurate and up to date information about the procedure and the risks of donation and have the opportunity to discuss the issue privately with a member of the healthcare team or a counsellor. Normally this information will include:

- The risks of becoming a living donor,
- The tests that are undertaken to assess suitability for donation and that this may reveal previously unsuspected health problems,
- What will happen before, during and after donation takes place, and
- In the case of solid organs, the long-term implications of living without the donated organ.

25. Prospective donors should be given the opportunity to ask questions about donation and should have their questions answered sensitively and intelligibly.

26. Procedures should be in place to ensure that living donors are acting voluntarily and free from pressure or coercion. In order to avoid donors being paid and then posing as a known donor, independent checks should also be undertaken to verify the claimed relationship and, where this cannot be proven, the donation should not proceed. Such checks should be independent of the transplant team and those who are caring for the potential recipient.

27. Additional safeguards should be in place for vulnerable donors, including but not limited to, people who are dependent in some way (such as competent minors donating to a parent or sibling).

28. Prisoners should be eligible to be living donors only in exceptional circumstances, to first or second degree

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family members; evidence should be provided of any claimed relationship before the donation may proceed. Where prisoners are to be considered as living donors, extra safeguards are required to ensure they are acting voluntarily and are not subject to coercion.

29. Those who lack the capacity to consent should not be considered as living organ donors because of their inability to understand and decide voluntarily. Exceptions may be made in very limited circumstances, following legal and ethical review.

30. Donors should not lose out financially as a result of their donation and so should be reimbursed for general and medical expenses and any loss of earnings incurred.

31. In some parts of the world individuals are paid for donating a kidney, although in virtually all countries the sale of organs is unlawful. The WMA is strongly opposed to a market in organs.

PROTOCOLS FOR RECIPIENTS

32. Protocols for free and informed decision making should be followed in the case of recipients of organs or tissue. Normally, this will include providing information about:

- The risks of the procedure,
- The likely short, medium and long-term survival, morbidity, and quality-of-life prospects,
- Alternatives to transplantation, and
- How organs and tissues are obtained.

33. In the case of a delayed diagnosis for infection, disease or malignancy in the donor, there should be a strong presumption that the recipient will be informed of any risk to which they may have been exposed. Individual decisions about disclosure need to take account of the particular circumstances, including the level and severity of risk. In most cases disclosure will be appropriate and should be managed carefully and sensitively.

COSTS AND ORIGIN OF ORGANS AND TISSUES

34. Organs or tissue suspected to have been obtained through unlawful means must not be accepted for transplantation.

35. Organs and tissues must not be sold for profit. In calculating the cost of transplantation, charges related to the organ or tissue itself should be restricted to those costs directly associated with its retrieval, storage, allocation and transplantation.

36. Transplant surgeons should seek to ensure that the organs and tissues they transplant have been obtained in accordance with the provisions of this policy and should refrain from transplanting organs and tissues that they know, or suspect, have not been procured in a legal and ethical manner.

TRANSPARENCY AND ACCOUNTABILITY

37. National Medical Associations should work with governments and relevant institutions to ensure that appropriate, effective structures and processes are in place to:

- support relevant traceability and follow-up of all transplant recipients and living donors including those who require ongoing medical management receive care and support;
- record information on donation and transplantation rates and outcomes;
- assess the short and long-term outcomes, quality, safety and efficacy of organ donation and transplantation activities;
- assess the adherence to ethical and clinical protocols of organ donation and transplantation activities;

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38. The data arising from these activities should be publicly accessible and open to scrutiny (notwithstanding appropriate protection of donor and recipient confidentiality).

FUTURE OPTIONS

39. Public health measures to reduce the demand for donated organs should be seen as a priority, alongside initiatives to increase the effectiveness and success of organ donation systems.

40. New developments and possibilities, such as xenotransplantation and the use of stem cell technology to repair damaged organs, should be monitored. Before their introduction into clinical practice such technologies should be subject to scientific review and robust safety checks as well as ethical review. Where, as with xenotransplantation, there are potential risks that go beyond individual recipients, this process must also involve public debate.