

WMA STATEMENT ON GENETICS AND MEDICINE

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and amended by the 60th WMA General Assembly, New Delhi, India, October 2009

PREAMBLE

1. In recent years, the field of genetics has undergone rapid change and development. The areas of gene therapy and genetic engineering and the development of new technology have presented possibilities inconceivable only decades ago.
2. The Human Genome Project opened new spheres of research. Its applications also proved useful to clinical care, by allowing physicians to utilize knowledge of the human genome in order to diagnose future disease as well as to individualize drug therapy (pharmacogenomics).
3. Because of this, genetics has become an integral part of primary care medicine. Whereas at one time, medical genetics was devoted to the study of relatively rare genetic disorders, the Human Genome Project has established a genetic contribution to a variety of common diseases. It is therefore incumbent upon all physicians to have a working knowledge of the field.
4. Genetics is an area of medicine with enormous medical, social, ethical and legal implications. The WMA has developed this statement in order to address some of these concerns and provide guidance to physicians. These guidelines should be up-dated in accordance with developments in the field of genetics.

MAJOR ISSUES:

Genetic testing

5. The identification of disease-related genes has led to an increase in the number of available genetic tests that detect disease or an individual's risk of disease. As the number and types of such tests and the diseases they detect increases, there is concern about the reliability and limitations of such tests, as well as the implications of testing and disclosure. The ability of physicians to interpret test results and counsel their patients has also been challenged by the proliferation of knowledge.
6. Genetic testing may be undergone prior to marriage or childbearing to detect the presence of carrier genes that might affect the health of future offspring. Physicians should actively inform those from populations with high incidence of certain genetic diseases about the possibility of pre-marital and pre-pregnancy testing, and genetic counselling

- should be made available to those individuals or couples who are considering such testing.
7. Genetic counselling and testing during pregnancy should be offered as an option. In cases where no medical intervention is possible following diagnosis, this should be explained to the couple prior to their decision to test.
 8. In recent years, with the advent of IVF, genetic testing has been extended to pre-implantation genetic diagnosis of embryos (PGD). This can be a useful tool in cases where a couple has a high chance of conceiving a child with genetic disease.
 9. Since the purpose of medicine is to treat, in cases where no sickness or disability is involved, genetic screening should not be employed as a means of producing children with pre-determined characteristics. For example, genetic screening should not be used to enable sex selection unless there is a gender-based illness involved. Similarly, physicians should not countenance the use of such screening to promote non-health related personal attributes.
 10. Genetic testing should be done only with informed consent of the individual or his/her legal guardian. Genetic testing for predisposition to disease should be performed only on consenting adults, unless there is treatment available for the condition and the test results would facilitate earlier instigation of this treatment.
 11. Valid consent to genetic testing should include the following factors:
 - The limitations of genetic testing, including the fact that the presence of a specific gene may denote predisposition to disease rather than the disease itself and does not definitively predict the likelihood of developing a certain disease, particularly in multi-factorial disorders.
 - The fact that a disease may manifest itself in one of several forms and in varying degrees. Information about the nature and predictability of information received from the tests.
 - The benefits of testing including the relief of uncertainty and the ability to make informed choices, including the possible need to increase or reduce regular screenings and checkups and to implement risk reduction measures.
 - The implications of a positive result and the prevention, screening and/or treatment possibilities.
 - The possible implications for the family members of the patient involved.
 12. In the case of a positive test result that may have implications for third parties such as close relatives, the individual tested should be encouraged to discuss the results of the test with such third parties. In cases where not disclosing the results involves a direct and imminent threat to the life or health of an individual, the physician may reveal the results to such third parties, but should usually discuss this with the patient first. If the physician has access to an ethics committee, it is preferable to consult such a committee prior to revealing results to third parties.

Genetic counselling

13. Genetic counselling is generally offered prior to marriage or conception, in order to predict the likelihood of conceiving an affected child, during pregnancy, in order to determine the condition of the fetus, or to an adult, in order to determine susceptibility to a certain disease.
14. Individuals at higher risk for conceiving a child with a specific disease should be offered genetic counselling prior to conception or during pregnancy. In addition, adults at higher risk for various diseases such as cancer, mental illness or neurodegenerative diseases in which the risk can be tested for, should be made aware of the availability of genetic counselling.
15. Because of the scientific complexity involved in genetic testing as well as the practical and emotional implications of the results, the WMA sees great importance in educating and training medical students and physicians in genetic counselling, particularly counselling related to pre-symptomatic diagnosis of disease. Independent genetic counsellors also have an important role to play. The WMA acknowledges that there can be very complex situations requiring the involvement of medical genetics specialists.
16. In all cases where genetic counselling is offered, it should be non-directive and protect the individual's right not to be tested.
17. In cases of counselling prior to or during pregnancy, the prospective parents should be given information to provide the basis for an informed decision regarding child-bearing, but should not be influenced by the physicians' personal views in this matter and physicians should be careful not to substitute their own moral judgment for that of the prospective parents. In cases where a physician is morally opposed to contraception or abortion, he/she may choose not to provide these services but should alert prospective parents that a potential genetic problem exists and make note of the option of contraception or abortion as well as treatment alternatives, relevant genetic tests, and the availability of genetic counselling.

Confidentiality of results

18. Like all medical records, the results of genetic testing should be kept strictly confidential, and should not be revealed to outside parties without the consent of the individual tested. Third parties to whom results may in certain circumstances be released are identified in paragraph 12.
19. Physicians should support the passage of laws guaranteeing that no individual shall be discriminated against on the basis of genetic makeup in the fields of human rights, employment and insurance.

Gene therapy and genetic research

20. Gene therapy represents a combination of techniques used to correct defective genes that cause disease, especially in the fields of oncology, hematology and immune disorders. Gene therapy is not yet an active current therapy but is still in a stage of clini-

cal investigation. However, with the continued development of this field, it should proceed according to the following guidelines:

- Gene therapy performed in a research context should conform to the requirements of the Declaration of Helsinki while therapy performed in a treatment context should conform to standards of medical practice and professional responsibility.
 - Informed consent should always be obtained from the patient undergoing the therapy. This informed consent should include disclosure of the risks of gene therapy, including the fact that the patient may have to undergo multiple rounds of gene therapy, the risk of an immune response, and the potential problems arising from the use of viral vectors.
 - Gene therapy should only be undertaken after a careful analysis of the risks and benefits involved and an evaluation of the perceived effectiveness of the therapy, as compared to the risks, side effects, availability and effectiveness of other treatments.
21. It is currently possible to undertake screening of an embryo in order to provide stem cell or other therapies for an existing sibling with a genetic disorder. This may be considered acceptable medical practice where no evidence exists that the embryo is being created exclusively for this purpose.
 22. Genetic discoveries should be shared as much as possible between countries so as to benefit humankind and reduce duplication of research and the risk inherent in research in this area.
 23. The mapping of human genomes must be anonymous but the information acquired will apply to every human being. The genetic information should be general property. Therefore, no patents should be given for the human genome or parts of it.
 24. In the case of genetic research performed on large, defined population groups, efforts should be made to avoid potential stigmatization.

Cloning

25. Recent developments in science have led to the cloning of a mammal and raise the possibility of such cloning techniques being used in humans.
26. Cloning includes both therapeutic cloning, namely the cloning of individual stem cells in order to produce a healthy copy of a diseased tissue or organ for transplant, and reproductive cloning, namely the cloning of an existing mammal to produce a duplicate of such mammal. The WMA currently opposes reproductive cloning, and in many countries it is considered to pose more of an ethical problem than therapeutic cloning.
27. Physicians should act in accordance with the codes of medical ethics in their countries regarding the use of cloning and be mindful of the law governing this activity