WMA DECLARATION OF REYKJAVIK – ETHICAL CONSIDERATIONS REGARDING THE USE OF GENETICS IN HEALTH CARE

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PREAMBLE

Genetics contributes to the growing understanding of the causes, developments, classifications and treatments of diseases. The use of genetics is increasing, moving from the identification of monogenic diseases and use in cancer treatment towards predicting risks of multifactorial diseases and manipulation of individual genes. In these ways, the use of genetics does and increasingly will create great value at an individual as well as at a societal level. However, the use of genetic information about individuals also raises issues concerning confidentiality, privacy and the risk of psychological distress, stigmatization, and discrimination.

This declaration provides recommendations for the use of medical genetics that respects the ethical challenges that such use entails. It is primarily aimed at the use of genetics in the provision of health care. The collection, storage and use of genetic data beyond the individual care of patients should adhere to the principles put forward in the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. The use of genetics in medical research involving human subjects, including research on identifiable human material and data, should adhere to the principles put forward in the WMA Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.

This Declaration should be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs. The declaration should be updated in accordance with developments in the field of genetics.

Genetic information has characteristics that are ethically significant. Individually, these characteristics can also be found in other types of health care information. However, the combination of these characteristics makes genetic information particularly sensitive. This sensitivity – combined with the intense interest in genetic information from many different stakeholders – underscores the importance of respecting the fundamental principles of medical ethics, particularly the patient's right to autonomy, confidentiality, privacy and benefit in relation to generating, storing, using or sharing genetic information.

Central among the ethically significant characteristics are:

- Genetic information is identifying for an individual.
- Genetic analysis can generate extensive and detailed information about an individual.
- Genetic analysis may generate additional findings.
- The full significance of the information generated by genetic analysis is not yet known.
- Genetic information about an individual cannot be fully anonymized, and de-identified genetic information may be re-identified.

- Genetic data contains information not only about the individual who has undergone testing, but also about individuals who are genetically related to the tested individual.
- Genetic testing of one individual may entail that the physician asks for access to health care information about – or genetic testing of – genetically related persons (family members).

ETHICAL PRINCIPLES

Benefit

Genetic testing in the context of healthcare provision should primarily be done for the benefit of the patient being tested.

Relevance

Genetics test should not be wider in scope than what is relevant for the purpose of the test.

Informed consent

1. Genetic testing should only be done with the informed consent of the individual or his/her legal guardian. Genetic testing for predisposition to disease should be performed on children only if there are clear clinical indications and being aware of the test results would be in the best interests of the child.
2. The consent process must include providing the patient with understandable, accurate and adequate information about the following:
    - The purpose, nature and benefits of the test.
    - The risks, burdens and limitations of the test.
    - The nature and significance of the information to be generated by the test.
    - The procedures for return of results including additional findings and future discoveries.
    - The options for responding to the results, including possible treatments.
    - How, where, and for how long the test results, data and biological samples will be stored, and who can gain access to current and future results.
    - The possible secondary uses of the information generated by the test
    - The measures protecting confidentiality, privacy and autonomy, including data security measures
    - The procedures for managing results that have implications for genetically related persons
    - When applicable, commercial use and benefit sharing, intellectual property issues and the transfer of data or material to third parties.

Additional findings (secondary and incidental findings)

1. A genetic test may generate additional findings that are not related to the primary purpose of the test, also referred to as secondary or incidental findings. Procedures for handling such findings should be determined before the test, and information about these procedures should be communicated to the patient as part of the consent process.
2. The principles for managing additional findings must include consideration for:

- The patient's preferences regarding the management of additional findings.
- The significance of the additional findings for the patient's health and other interests.
- The significance of the findings for the health and other interests of persons who are genetically related to the patient.
- The scientific validity of the additional findings.
- The strengths of the evidence for the correlation between the additional findings and health related risks for the patient.
- The degree to which the additional findings are actionable, medically or otherwise.

Genetic counselling

1. Appropriate genetic counselling should always be offered when genetic tests or genetics-based treatments are offered or performed and for the interpretation of results. Counselling should enable the patient to make informed decisions according to their own values and interests. Counselling must not be biased by the personal values of the counsellor. The individual's right not to be tested should be protected, and if the individual has been tested, there should be no obligation for the individual to act on the results of the test.

2. Medical students and physicians should receive education and training in genetic counselling, particularly counselling related to pre-symptomatic diagnosis of disease.

Confidentiality

Like all medical records, information from genetic testing or genetic therapy must be kept strictly confidential and must not be revealed to third parties in identifiable form without the consent of the individual tested. Third parties, to whom results may in certain circumstances be released, are identified in paragraph 15.

Informing third parties

In the case of a 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 an expected harm that is serious and unavoidable except by disclosure, and clearly greater than the harm likely to result from disclosure, the physician may reveal necessary information to such third parties without the consent of the patient 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 information to third parties.

Data protection

The collection, storage and use of genetic data requires the highest level of data protection.

Discrimination

No individual or group must be discriminated against in any way based on genetic makeup, including the fields of human rights, employment and insurance. This protection should apply to those individuals who have undergone genetic testing or genetic therapy as well as those individuals about whom genetic information can be inferred. Particular care should be taken to protect vulnerable individuals and groups.

Cost of testing

The decision to include genetic analysis as part of medical care can introduce significant cost for the patient and the health care system. Therefore, such a decision should always be based on the expectation that the costs of the analysis are justified by the benefits for the patient.

Reliability and limitations

1. The identification of disease-related genes has led to an increase in the number of available genetic tests,

analyses and treatments. As the number, types and complexity of these increase, great care must be taken to ensure their reliability, accuracy and quality and to inform patients about their limitations.

2. The benefit of a genetic test for an individual may depend on the availability of information about the relevant background population. Medical professionals should be aware of the scope and the limitations of genetic background data and health information stored in databases used in providing clinical genetic testing services.

Direct-to-consumer tests

If genetic tests are offered directly to consumers for medical purposes, they must meet the same technical, professional, legal and ethical standards as tests offered by certified laboratories and must be in accordance with the recommendations put forward in this statement. In particular, providers of direct-to-consumer tests must provide understandable, accurate and adequate information about the reliability and limitations of their services.

Clinical use of data from research

For research projects that involve genetic testing, and where the participant can be identified, the research participant must be informed about the possibility of findings that indicate a serious threat to the health of the participant. If there are such findings, the participant should be offered a referral to genetic counseling and appropriate medical intervention.

Gene therapy and editing

Gene therapy and editing represents a combination of techniques used to manipulate disease related genes. The use of these techniques should adhere to the following guidelines:

- The use of gene therapy and somatic genome editing should conform to standards of medical ethics and professional responsibility.
- Patient autonomy should be respected, and informed consent should always be obtained. This informed consent process should include disclosure of the risks of gene therapy and editing, including the fact that the patient may have to undergo multiple rounds of gene therapy, the risk of an immune response, the potential problems arising from the use of viral vectors and off-target genome effects.
- Gene therapy and editing 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.
- Gene editing of germline cells has scientifically unresolved risks and should not be clinically applied. This does not preclude testing gene editing or other similar research.

Cloning

Cloning includes both therapeutic cloning, namely the cloning of individual stem cells to produce a healthy copy of a diseased tissue or organ for transplant, and reproductive cloning, namely the cloning of an existing human to produce a genetic duplicate of that human. The WMA opposes reproductive cloning of humans.