

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION No. R (92) 3

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

ON GENETIC TESTING AND SCREENING FOR HEALTH CARE PURPOSES¹

*(Adopted by the Committee of Ministers on 10 February 1992
at the 470th meeting of the Ministers' Deputies)*

The Committee of Ministers, under the terms of Article 15.b of the Statute of the Council of Europe,
Considering that the aim of the Council of Europe is to achieve a greater unity between its members ;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 and the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981 ;

Having regard to the Recommendations of the Committee of Ministers No. R (90) 3 on medical research on human beings, No. R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling, and No. R (92) 1 on the use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system ;

Bearing in mind that recent progress in the field of biomedical science has made it possible to obtain a greater knowledge of the human genome and the nature of genetic disorders ;

Recognising the benefits and potential usefulness of these techniques not only for the individual, but also for the family and other relatives, as well as for the population as a whole ;

Aware that the introduction of genetic testing and screening also arouses anxiety and that it is therefore desirable to give assurances as to their proper use ;

Bearing in mind that rules governing the collection and use of medical data also apply to genetic data collected and used for health care purposes, including medical research ;

Recognising the need for education of the members of the health care professions and the general public about the importance of genetic factors to health, and for including this subject in curricula for general and further education, both at school and at university level, and in professional training ;

1. When this Recommendation was adopted and in application of Article 10.2.c of the Rules of Procedure for the meetings of the Ministers' Deputies ;

– the Representative of the Netherlands reserved the right of his government to comply or not with principle 7 of the recommendation ;

– the Representative of Germany reserved the right of his government to comply or not with the words "and/or to avoid giving birth to affected offspring", in the third indent of sub-paragraph a of the paragraph on "Purpose, scope and definitions" of the recommendation.

Considering that each country must determine its own special needs in order to develop the most appropriate services;

Recognising that it should be the goal of every country to offer its citizens equal opportunity of access to genetic testing and screening services;

Aware of the dangers of discrimination and social stigmatisation which may result from genetic information, and determined to fight such phenomena,

Recommends that the governments of the member states

- a. be guided in their legislation and policy by the principles and recommendations set out below;
- b. promote in their educational systems the teaching of human genetics.

Principles and recommendations

Purpose, scope and definitions

The purpose of this recommendation is to ensure respect for certain principles in the field of genetic testing and screening for health care purposes, including medical research.¹

For the purposes of this recommendation:

- a. the term “genetic tests for health care purposes” refers to tests which serve:
 - to diagnose and classify a genetic disease;
 - to identify unaffected carriers of a defective gene in order to counsel them about the risk of having affected children;
 - to detect a serious genetic disease before the clinical onset of symptoms in order to improve the quality of life using secondary preventive measures and/or to avoid giving birth to affected offspring;
 - to identify persons at risk of contracting a disease where both a defective gene and a certain life-style are important as causes of the disease;
- b. the term “genetic diagnosis” refers to tests carried out to diagnose a presumed ailment on an individual or several members of a family, in the framework of a family study;
- c. the term “genetic screening” refers to genetic tests carried out on a population as a whole or a subset of it without previous suspicion that the tested individuals may carry the trait.²

I. Rules for good practice in genetic testing and screening

Principle 1 – Informing the public

- a. Plans for the introduction of genetic testing and screening should be brought to the notice of individuals, families and the public.
- b. The public should be informed about genetic testing and screening, in particular their availability, purpose and implications – medical, legal, social and ethical – as well as the centres where they are carried out. Such information should start within the school system and be continued by the media.

Principle 2 – Quality of genetic services

- a. Proper education should be provided regarding human genetics and genetic disorders, particularly for health professionals and the paramedical professions, but also for any other profession concerned.

1. Genetic testing and screening can be carried out at different levels, such as on chromosomes, genes (DNA), proteins, organs or a given individual, and can be complemented with aspects of the family history.

2. The essential distinction between genetic diagnosis and genetic screening is that the latter is not initiated by the individual who is its subject, but by the provider of the screening service.

- b. Genetic tests may only be carried out under the responsibility of a duly qualified physician.
- c. It is desirable for centres where laboratory tests are performed to be approved by the state or by a competent authority in the state, and to participate in an external quality assurance.

Principle 3 – Counselling and support

- a. Any genetic testing and screening procedure should be accompanied by appropriate counselling, both before and after the procedure.

Such counselling must be non-directive. The information to be given should include the pertinent medical facts, the results of tests, as well as the consequences and choices. It should explain the purpose and the nature of the tests and point out possible risks. It must be adapted to the circumstances in which individuals and families receive genetic information.

- b. Everything should be done to provide, where necessary, continuing support for the tested persons.

II. Access to genetic tests

Principle 4 – Equality of access – non-discrimination

- a. There should be equality of access to genetic testing, without financial considerations and without preconditions concerning eventual personal choices.
- b. No condition should be attached to the acceptance or the undergoing of genetic tests.
- c. The sale to the public of tests for diagnosing genetic diseases or a predisposition for such diseases, or for the identification of carriers of such diseases, should only be allowed subject to strict licensing conditions laid down by national legislation.

Principle 5 – Self-determination

- a. The provision of genetic services should be based on respect for the principle of self-determination of the persons concerned. For this reason, any genetic testing, even when offered systematically, should be subject to their express, free and informed consent.
- b. The testing of the following categories of persons should be subject to special safeguards:
 - minors;
 - persons suffering from mental disorders;
 - adults placed under limited guardianship.

Testing of these persons for diagnostic purposes should be permitted only when this is necessary for their own health or if the information is imperatively needed to diagnose the existence of a genetic disease in family members.

The consent of the person to be tested is required, except where national law provides otherwise.

Principle 6 – Non-compulsory nature of tests

- a. Health service benefits, family allowances, marriage requirements or other similar formalities, as well as the admission to, or the continued exercise of, certain activities, especially employment, should not be made dependent on the undergoing of genetics tests or screening.

Exceptions to this principle must be justified by reasons of direct protection of the person concerned or of a third party and be directly related to the specific conditions of the activity.

- b. Only if expressly allowed by law may tests be made compulsory for the protection of individuals or the public.

Principle 7 – Insurance

Insurers should not have the right to require genetic testing or to enquire about results of previously performed tests, as a pre-condition for the conclusion or modification of an insurance contract.

III. *Data protection and professional secrecy*

Principle 8 – Data protection

a. The collection and storage of substances and of samples, and the processing of information derived therefrom, must be in conformity with the Council of Europe's basic principles of data protection and data security laid down in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, European Treaty Series No. 108 of 28 January 1981 and the relevant recommendations of the Committee of Ministers in this field.

In particular in genetic screening and testing or associated genetic counselling personal data may be collected, processed and stored only for the purposes of health care, diagnosis and disease prevention, and for research closely related to these matters, as outlined in Principle 5.

b. Nominative genetic data may be stored as part of medical records and may also be stored in disease-related or test-related registers. The establishment and maintenance of such registers should be subject to national legislation.

Principle 9 – Professional secrecy

Persons handling genetic information should be bound by professional rules of conduct and rules laid down by national legislation aimed at preventing the misuse of such information and, in particular, by the duty to observe strict confidentiality. Personal information obtained by genetic testing is protected on the same basis as other medical data by the rules of medical data protection.

However, in the case of a severe genetic risk for other family members, consideration should be given, in accordance with national legislation and professional rules of conduct, to informing family members about matters relevant to their health or that of their future children.

Principle 10 – Separate storage of genetic information

Genetic data collected for health care purposes, as for all medical data, should as a general rule be kept separate from other personal records.

Principle 11 – Unexpected findings

In conformity with national legislation, unexpected findings may be communicated to the person tested only if they are of direct clinical importance to the person or the family.

Communication of unexpected findings to family members of the person tested should only be authorised by national law if the person tested refuses expressly to inform them even though their lives are in danger.

IV. *Research*

Principle 12 – Supervision

Research projects involving medical genetic data have to be carried out, in conformity with the standards of medical ethics, under the direct supervision of a responsible physician or, in exceptional circumstances, of a responsible scientist.

Principle 13 – Handling of data

a. Samples collected for a specific medical or scientific purpose may not, without permission of the persons concerned or the persons legally entitled to give permission on their behalf, be used in ways which could be harmful to the persons concerned.

b. The use of genetic data for population and similar studies has to respect rules governing data protection, and in particular concerning anonymity and confidentiality. The same applies to the publishing of such data.