

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

RECOMMENDATION No. R (90) 13

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES

**ON PRENATAL GENETIC SCREENING, PRENATAL GENETIC DIAGNOSIS
AND ASSOCIATED GENETIC COUNSELLING**

*(Adopted by the Committee of Ministers on 21 June 1990
at the 442nd 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, in particular by the adoption of common rules on matters of common interest;

Aware of the Council of Europe's vocation for safeguarding the moral values which are the common heritage of the member states, based essentially on respect for life and human dignity;

Reaffirming its commitment to personal freedom and respect for private and family life;

Having regard to the Convention for the Protection of Human Rights and Fundamental Freedoms (1950), the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (1981) and other relevant international instruments;

Having regard to Recommendation 934 (1982) on genetic engineering of the Parliamentary Assembly of the Council of Europe as well as the World Medical Association's Madrid Statement (1987) on genetic counselling and genetic engineering;

Recognising the continuing relevance of the detailed principles contained in Recommendation No. R (81) 1 on regulations for automated medical data banks for the collection, storage and processing of personal data, but believing nevertheless that it is necessary to make specific provision for such data in the context of prenatal screening and diagnosis and associated genetic counselling;

Noting that in recent decades considerable progress has been achieved in detecting genetic abnormalities in the child to be born through genetic screening and through prenatal diagnosis of pregnant women, but also noting the fears that these procedures arouse;

Considering that women of child-bearing age and couples should be fully informed and educated about the availability of, the reasons for and risks of such procedures;

Convinced that the genetic diagnosis and screening must always be accompanied by appropriate genetic counselling but that such counselling should in no case be of a directive nature and must always leave the woman of child-bearing age fully informed so as to enable her to take a free decision;

Aware of the role that the mass media play in informing and educating the public, and considering therefore that it is appropriate that they should be better and regularly informed about progress, practice, availability, ethical issues and ethical principles relating to prenatal screening and diagnosis and, in particular, procedures used for prenatal genetic screening and diagnosis;

Aware of the fear that prenatal screening and diagnosis could adversely affect social attitudes towards the handicapped and wishing that all necessary measures should be taken to ensure that society's attitude and behaviour is not so affected;

Considering that the use of these procedures should be governed by ethical, medical, legal and social principles in order to prevent any abuse,

Recommends the governments of the member states to adopt legislation in conformity with the principles contained in this recommendation or to take any other measures to ensure their implementation.

Principles

Scope and definitions

For the purpose of these principles, "prenatal genetic screening" is the term used to describe screening tests carried out to identify among the general population of apparently healthy individuals those at risk of transmitting a genetic disorder to their offspring. Prenatal genetic screening may take place during pregnancy and may involve testing people of either sex.

The principles also cover premarital and preconception screening which are undertaken to identify a risk to the health of the future child.

"Prenatal diagnosis" is the term used to describe tests used to determine whether or not an individual embryo or foetus is affected by a specific disorder.

Principle 1

No prenatal genetic screening and/or prenatal genetic diagnosis tests should be carried out if counselling prior to and after the tests is not available.

Principle 2

Prenatal genetic screening and/or prenatal genetic diagnosis tests undertaken for the purpose of identifying a risk to the health of an unborn child should be aimed only at detecting a serious risk to the health of the child.

Principle 3

Prenatal genetic screening and prenatal genetic diagnosis should only be carried out under the responsibility of a physician; laboratory procedures must be carried out in qualified institutions which have been approved by the state or by a competent authority of the state to conduct such procedures.

Principle 4

The counselling must be non-directive; the counsellor should under no condition try to impose his or her convictions on the persons being counselled but inform and advise them on pertinent facts and choices.

Principle 5

The participation of both members of the couple in the counselling sessions should be encouraged.

Principle 6

Prenatal genetic screening and prenatal genetic diagnosis may only take place with the free and informed consent of the person concerned.

Special care is needed for legally incapacitated persons to ensure that they are not denied access to prenatal genetic screening and prenatal genetic diagnosis on account of the legal incapacity and that their legal representative or an authority or person designated under national law is consulted on their behalf. Prenatal genetic screening or prenatal genetic diagnosis should not be carried out when the person to undergo tests objects.

Principle 7

When prenatal genetic screening and prenatal genetic diagnosis are offered routinely, this by no means does away with the requirement of free and informed consent.

Principle 8

The information given during the counselling prior to prenatal genetic screening and prenatal genetic diagnosis must be adapted to the person's circumstances and be sufficient to reach a fully informed decision. This information should in particular cover the purpose of the tests and their nature as well as any risks which these tests present.

Principle 9

In order to protect the woman's freedom of choice, she should not be compelled by the requirements of national law or administrative practice to accept or refuse screening or diagnosis. In particular, any entitlement to medical insurance or social allowance should not be dependent on the undergoing of these tests.

Principle 10

No discriminatory conditions should be applied to those who seek or to those who do not seek prenatal screening or diagnostic testing, where these are appropriate.

Principle 11

In prenatal genetic screening, prenatal genetic diagnosis or associated genetic counselling, personal data may only be collected, processed and stored for the purposes of medical care, diagnosis and prevention of disease, and research closely related to medical care. Such data should be collected, processed and stored in accordance with the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data and the Committee of Ministers' Recommendation No. R (81) 1 on regulations for automated medical data banks.

Principle 12

Any information of a personal nature obtained during prenatal genetic screening and prenatal genetic diagnosis must be kept confidential.

Principle 13

The right of access to personal data collected pursuant to prenatal genetic screening and prenatal genetic diagnosis should be given only to the data subject in the normal manner required for personal health data in accordance with national law and practice. Genetic data which relate to one member of the couple should not be communicated to the other member of the couple without the free and informed consent of the former.

Principle 14

Where there is an increased risk of passing on a serious genetic disorder, access to preconception counselling and, if necessary, premarital and preconception screening and diagnostic services should be readily available and widely known.