

Additional Protocol to the Oviedo Convention concerning Genetic Testing for Health Purposes

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Council of Europe: activities in the field of bioethics

- **Council of Europe**: intergovernmental organisation set up in 1949
- 47 member states
- General objectives: **protection of human rights**, democratic stability, rule of law and to find common solution to the challenges facing European society
- Objectives of **activities in bioethics**:
To protect human dignity and fundamental rights in the field of biomedicine

→ Activities of the **Council of Europe**:
Defining fundamental principles to that end

Genetic testing is:

a source of progress...

and ethical challenges

Genetic tests: ethical concerns

- Easier access to « biological intimacy » of individuals
 - Risks for private life of:
 - person concerned
 - members of his/her family
 - Risks of discrimination (abusive use by a third party : e.g. employment, insurance)

Problems raised in the field of health

- Capacity of analysis greater than capacity to act (« prevention » or treatment)
- Difficulty to understand the implications of the test
- Difficulty of interpretation of test results
- Risk for private life (person concerned and his/her family)
- Persons not able to consent

Additional Protocol concerning Genetic Testing for Health Purposes

- Builds on and complements the principles laid down in the **Convention on Human Rights and Biomedicine** (European patient rights instrument)
- Scope: tests involving **analysis** of biological samples, to identify genetic **characteristics inherited or acquired during early prenatal development**
- Does not apply to:
 - tests on embryo or foetus
 - tests for research purposes

Additional Protocol: provisions (1)

- **Non discrimination** and non stigmatisation on the basis of genetic characteristics (Article 4)
- **Genetic services** (Article 5)
 - Tests: scientific and **clinical validity**
 - Laboratories: **quality insurance** program, regular monitoring
 - Persons: appropriate qualifications to perform their role (professional obligations and standards)
- **Clinical utility** (Article 6): essential criteria for deciding to offer a test

Additional Protocol: provisions (2)

- **Individualised supervision** (article 7)
 - **Genetic test for health purposes only under individualised medical supervision**
 - ◆ Exceptions may be allowed by countries, but only if implications not important
 - **To facilitate access to objective general information on genetic testing** (article 20)
- **Information and genetic counselling** (article 8)
 - Appropriate genetic counselling available for predictive tests (as well as healthy carrier testing)
- **Free informed consent** (article 9)
 - Documented for predictive test

Additional Protocol: provisions (3)

- **Persons no able to consent** (articles 10 to 12)
 - Opinion of the minor taken into consideration
 - Previously expressed wishes respected
- **Tests for the benefit of family members**
 - On person not able to consent (Article 13)
 - ◆ Exceptional and under strict conditions
- **Tests on deceased persons** (Article 15)

Additional Protocol: provisions (4)

- Respect for private life and right to information (Article 16)
- Information relevant to family members (Article 18)
 - Obligation to inform the person tested
- Genetic screening program for health purposes (Article 19)
- Reexamination no later than 5 years after entry into force

Conclusions

- Genetic testing
 - To continue to be source of progress for health care
 - New ethical challenges
- Additional Protocol concerning Genetic Testing for Health Purposes
 - First and only international legally binding instrument in this field
 - Framework for the protection of human rights and fundamental freedoms with regards to genetic testing for health purposes
 - Follow up in particular on over the counter tests
- Council of Europe current activity:
 - Predictivity, genetic testing in the field of insurance