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:
  - Predicitivity, genetic testing in the field of insurance