

The Oviedo Convention

**A fundamental reference for
the protection of human
rights in the field of
biomedicine**

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The Convention on Human Rights and Biomedicine

- The Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine
- Opened for signature 1997 in Oviedo (Spain)
- Signed by 31 countries
- Ratified by 26 countries

- 2009: 10th anniversary of its entry into force
→ **« An achievement and a starting point »**

A little bit of history

- After second world war:
 - **Treaties** governing **relationship between states and their citizens**
 - Reference: Universal Declaration of human rights (1948)
 - International Covenant on civil and political rights (1966)
 - Convention against torture (1984)
 - Convention on children's rights (1989)
 - ➔ Contribution to a coherent international system of principles focusing on individual rights
- Formal acknowledgement of universal principles: **insufficient**
- To look for mechanism for ensure respect of principles

Regional cooperation

- Response:
 - development of regional cooperation between states
- Objective: to ensure effectivity of these rights
 - Council of Europe (1949)
 - European Union (1957)
- Council of Europe: European Convention on Human Rights (1950)
 - Preamble: « *to take the first steps for the collective enforcement of certain of the Rights stated in the Universal Declaration;* »
 - Setting up of the European Court of Human Rights

The Oviedo Convention

- **First international legally binding instrument** in this field
 - Ethical and legal principles applicable to any medical act
 - Principles applicable to new biomedical technologies
- Close **link** with the **European Convention on Human Rights**
 - Principles, concepts, terminology
- **Framework Convention**
 - Principles to be developed in Additional Protocols
 - Convention and its Additional Protocols: conventional system
- Standards:
 - Individual rights directly applicable by tribunal
 - Consent (Art. 5)
 - Obligations for States to take legal measures to ensure their enforcement
 - Equity of access to health care (Art. 3)

The Oviedo Convention: patient rights instrument

- One of the objective of the Convention:
Codification of principles applying to daily medical practice - Contribution to their implementation
- Medical ethical rules traditionally grouped around four main principles:
 - Autonomy
 - Confidentiality
 - Beneficence/non malficence
 - Justice

The Oviedo Convention: patient rights instrument (2)

- **Autonomy**
 - Consent (Art. 5) - Previously expressed wishes (Art. 9)
 - Protection of person not able to consent
 - To be consulted (Art.6)
 - Direct benefice (Art. 6)
- **Confidentiality**
 - Protection of private life (Art. 10)
 - Medical secrecy: also necessary trust in health care

The Oviedo Convention: patient rights instrument (3)

- **Beneficence/non malficence**
 - Protection of integrity, including with regard to unknown risk (Art.16)
 - Respect of professional standards (Art.4)
- **Justice**
 - Equity of access to health care (Art.3)
- **Protection of human dignity**
 - Primacy of the human being (Art.2)
 - Non discrimination (Art. 11)
 - No sex selection of the embryo (Art. 14)
 - Non commercialisation of the body and its part (Art. 21)₈

The Oviedo Convention: biomedical research

- **Biomedical research** (Chapter V)
 - Freedom of research
 - First legally binding international instrument to affirm such freedom
 - But not absolute - Subject to human rights protection
 - Proportionality (risk/benefit)
 - Voluntary participation
 - Prior independent evaluation of scientific relevance and ethical acceptability
 - Transparency
 - International responsibility
- Research on the embryo
 - Prohibition of embryo creation
 - If research allowed, adequate protection
 - Cloning

The Oviedo Convention: transplantation - genetics

- **Genetics** (Chapter IV)
 - Non discrimination (Art. 11)
 - MAP not for sex selection (Art.14)
 - Predictive genetic tests only for health purposes and subject to appropriate genetic counselling (Art. 12)
 - Prohibition of intervention modifying genome of future generation (Art. 13)
- **Transplantation of organs** (Chapter VI)
 - Protection of the living donor and the recipient
 - Priority to cadaveric donation
 - No removal of person not able to consent

Legal aspects of the Convention

- Art.26.1: **Restrictions** on the exercise of the rights are possible provided they are:
 - prescribed by law
 - necessary (for public safety, prevention of crime, protecting public health or the rights of others)
 - proportionate
- Art. 26.2 Restrictions are not possible on some provisions (e.g. on Art.11, non discrimination, Art.14 non selection of sex, Art.17 containing protection, in the research context, for persons not able to consent Art.21 prohibition of financial gain)

The Convention on Human Rights and Biomedicine

- **An achievement ...**
 - First international legally binding instrument
 - Defines a general framework for the protection of fundamental rights and freedoms with regards to the applications of biology and medicine
 - No precise solution to complex questions
 - Framework of principles to avoid practices which are contrary to human dignity and human rights
 - Common basic standards
 - Country free to grant wider protection (Art. 27)
- But also a **starting point**
 - Additional Protocols developed
 - Impact on legislation and practices

The Oviedo Convention: 10 years later

- **Impact**
 - On legislation
 - On practices
- **Value**
 - National
 - Regional
 - International

Legal impact of the Oviedo Convention (2)

- A reference at **European** level...
 - The European patient's rights instrument
 - Reference in several EU directives
 - IVD Directive
 - Tissue Directive
 - Key reference for the European Group on Ethics of Science and New Technologies (EGE)
 - Ethical rules for FP7 framework programme
- As well as at **international** level
 - UNESCO Declaration on human rights and bioethics
 - UN reports - Professional declarations

Legal impact of the Oviedo Convention (1)

- Primary significance: legal authority
- Decisive impact on **national** legislation
 - Including in States not Party
 - Convention used as a reference for
 - Patient rights legislation
 - Human organ and tissues transplantation
 - Mental health
 - Genetics
 - Medically assisted procreation
 - Biomedical research and biobanks,...
- Role of explanatory report

Impact of the Oviedo Convention on practices

- Influence on deontological codes in number of countries
- Reference for numerous bodies: e.g. national ethics committees, research ethics committees, hospital ethics commissions, professional regulatory bodies
- Reference tool for education and continuous training programme in various fields
- Promotion of public debate

Challenges faced

- Legal difficulties
 - Science evolves and standards are rigid
 - Legal principles and clinical reality
- Conflicts on issues
 - Research on persons not able to consent
 - Embryo
 - Germ therapy
- Cultural differences
 - Autonomy of individual/ social norms
 - Role of the family

The Oviedo Convention : 10 years later

- Confirmation of its **value**
- Became a **reference**
 - National
 - Regional
 - International
- Timelessness of its provisions: establish principles making it possible to address future challenges
- Fundamental basis for national « decisions »
- Impact on the **case law of the Court of Human Rights**

The Oviedo Convention and European Court of Human Rights

- Article 29 of the Convention :
The Court may give advisory opinions on legal questions concerning the interpretation of the Convention
- No formal link however, **close correspondance between provisions**
 - Convergences:
 - protection of private life Art.10/Art.8
 - non discrimination Art.11/Art.14
 - Primacy of the human being Art. 2/Art.2,3 and 4
- Oviedo Convention became a **reference for the Court**

The Oviedo Convention and ECHR case law

- **Medically assisted procreation**
 - Vo v. France
 - Evans v. United Kingdom
 - S.H. and others v. Austria
- **Consent to medical treatment**
 - Glas v. United Kingdom
 - Juhnke v. Turkey
 - V.C. v. Slovakia

Current and future challenges

- **New developments** in the field of biomedicine: new threat to fundamental rights (e.g. biobanks, genetics, neurosciences)
- **Globalisation** of the issues addressed
- Threat to human rights due to **commercialisation** of health care and privatisation of health care coverage
 - « donation » of organs, tissues and cells
 - From solidarity to mutuality (underwriting)
- Globalisation vs. Individualism
- Rapid **transposition** of research results in biomedical or other fields (e.g. Brain imaging)

Possible tools

- To complement legal corpus
- To develop tools to facilitate implementation of principles
- To reinforce activities at the request of member states to meet specific problems
- To reinforce synergy and link between CoE and other intergovernmental organisations, in particular EU
- To promote public debate - in particular with young people

Conclusions

- The Convention: an achievement and a starting point
 - European patient rights instrument
 - A fundamental reference at international level
- Profound impact on legislation and practices
 - *« We will never praise enough the considerable achievement that the Oviedo Convention represents »* J.P. Costa, President of the ECHR
 - *“The Convention provides an ethical and legal framework, within which it is now possible to work safely and in confidence”* Prof. Joze Trontelj (Slovenia)
 - *« For Europe, willingness to combine trust in scientific progress and protection of ethical values determines a new form of responsibility »* Prof. Sadek Beloucif (France)
- Ratifications: formal acknowledgement of this engagement in the protection of those values