

Unit 6.4 Patient Rights





Objectives

- To collect and analyse the results of the survey on the status of the European Convention on Human Rights and Biomedicine and the status of patient rights/users of genetic services
- To evaluate the readiness of the Member States to adopt a common framework for the protection of the rights of patients/users of genetic services

Description of the work

- Summer/ autumn of 2005: the questionnaire
 - 2 contactpersons in each country of the EU
 - Distinction between “old” and “new” member states
- After having received the answers, country reports were produced (30 – 50 pages)
 1. All the countries which have signed and ratified
 2. All the countries which have signed, but not yet ratified
 3. All the countries which did not sign, nor ratify

Limitations

- Language problem
- Too wide spread of information
 - Questionnaire is limited to certain articles of the Oviedo Convention

Article 4 (Professional Standards), Chapter II (Consent), Chapter III (Private life and right to information), Chapter IV (Human Genome) and article 26 (Restrictions on the exercise of the rights).

Right to informed consent	
<u>Basic requirement:</u> <ul style="list-style-type: none"> • Yes/No 	
<u>Form of informed consent:</u> <ul style="list-style-type: none"> • WRITTEN (required?) 	
<ul style="list-style-type: none"> • ORAL/VERBAL 	
<ul style="list-style-type: none"> • NON-VERBAL (implicit, tacit) 	
<ul style="list-style-type: none"> • PRESUMED 	
<u>Burden of proof regarding information preceding consent:</u> <u>Physician or patient?</u>	
<u>Information preceding consent explicitly provided (no valid consent without information):</u> <ul style="list-style-type: none"> • Yes/No 	
<ul style="list-style-type: none"> • Exceptions? (e.g. presumed consent) 	

COUNTRY REPORT

Description of the work

□ Publications:

1. H.NYS, et al., “Patient Rights in EU Member States after the ratification of the Convention on Human Rights and Biomedicine”, *Health Policy* 2007, vol. 83, 223-235.
2. T.GOFFIN, et al. “Why eight EU Member States signed, but not yet ratified the Convention on Human Rights and Biomedicine”, *Health Policy* 2007, (in press).

Description of the Work

- European Ethical-Legal Papers
 - Why?
 - Which?
 - Czech Republic
 - Denmark
 - Estonia
 - Greece
 - Bulgaria
 - Cyprus
 - Hungary
 - Lithuania



European Ethical-Legal Papers

- Hard copies limited available
- PDF-files of the booklets available on
 - www.eurogentest.org
 - www.cbmer.be
- If you want to receive a hard copy of the booklets, please send an email to tom.goffin@med.kuleuven.be so we can add you to the mailinglist

Collaboration

- Close collaboration with Unit 6.3 ‘Ethical Issues’
 - Kris Dierickx & Pascal Borry
 - Collective publications
 - European Ethical-Legal Papers, N° 3, Genetic testing and Counselling, European Guidance (available on the EuroGentest-website and on www.cbmer.be)

The next months, years...

- European Ethical-Legal Papers:
 - 19 booklets to go
 - Next booklets: Portugal, Romania, Slovakia, Slovenia, Spain
- Article on the countries which have not signed, nor ratified: focus on the patient rights protection in these countries in comparison with the protection provided by the Convention on Human Rights and Biomedicine