



Southern European Regional Workshop
Defining the needs and means for more
partnership between Patients, Patient Organisations
and Other Stakeholders in Clinical Trials
24 and 25 March 2010, Athens, Greece



Charters of Patients' Rights

A summary and comparison of
Patients' Rights throughout Europe





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The Declaration of Helsinki

- The Declaration of Helsinki was first presented in 1975, since then, five further revisions have come out, the last being in 2008.
- Often used as a guideline for Patients' Rights Charters.
- The Declaration is not legally binding.
- Found strong similarities between declaration and Charters of most countries.



Divisions of Patients' Rights

- There are different Rights Charters for the different countries within the EU.
- The Patients' Rights Charters have been divided into four main categories:
 - Informed Consent
 - Patients' Right to information on own Health
 - Patients' Right to their Medical File
 - Patients' Right to Complain and to Compensation
- Certain Countries are in the process of amending their Charters.

Informed Consent

Consent:

Usually oral, special cases
 written= BE, BG, CZ, EE, FI,
 HU, LT, LU, NL, PL, SE, SI,
 SK, ES, FR, GR, PT

Written= DK, IE, CY

Not Specified= LV, UK, IT,
 MT

Minors:

Different rights= BG, CZ, DK, EE, IE,
 LT, SE, SI, SK, LV, NL, PL, UK, CY, ES,
 GR, MT, PT

No Information= BE, FI, HU, LU, FR,
 IT

Withdrawal:

Right to Withdraw= BE, BG,
 CZ, DK, EE, FI, HU, LT, LU, LV, NL, PL,
 SE, SI, SK, UK, CY, ES, FR, GR, IT, MT,
 PT

No info= IE



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Right to Information on Own Health

Right to know:

Not separate=

CZ, DK, EE, LU, PL SI,
FR, IT, PT

Separate Right=

BE, BG, FI, HU, LT, LV,
NL, SE, SK, UK, CY, ES,
GR

No info: IE, MT

Right not to know:

BE, BG, CZ, DK, EE, FI, HU, IE, LT,
LU, LV, NL, PL, SE, SI, SK, UK, CY,
ES, FR, GR, IT, MT, PT

Therapeutic Exception:

Don't have exception= BG, EE

No info= PL, SK, MT

Have exception= BE, CZ, DK, FI, HU,
IE, LT, LU, LV, NL, SE, SI, UK, CY, ES,
FR, GR, IT, PT



● = S Countries

Right to Medical File

Right to med file:

Have right to file= BE, BG,
CZ, DK, EE, FI, HU, IE, LT,
LU, LV, NL, PL, SE, SI, SK,
UK, **CY, ES, FR, IT, MT, PT**

Same as right to health
info= **GR**

Minors:

No info= BE, BG, CZ, DK, EE,
FI, HU, IE, LT, LU, LV, NL, PL,
SE, SI, SK, UK, **CY, ES, IT, MT,**
PT

Info on minors= **FR, GR**



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Right to Complain and Compensation

Complain:

Under Construction= LV,
NL

Have Right but no legal
binding= BE, BG, CZ, DK,
EE, FI, HU, IE, LT, LU, PL,
SE, SI, SK, UK, **CY, ES, FR,**
GR, IT, MT, PT

Compensation:

Under Construction= LV, NL

No Specific Provisions= **CY, ES**

No Info= BE, IE, LU, **IT**

Right to Compensation= BG, CZ,
DK, EE, FI, HU, LT, PL, SE, SI, SK,
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Charters of Patients' Rights

- Basic Findings revealed that different Regions and Countries do not differ significantly in their Patients' Rights Charters.

- Strength of the Patients' Rights Charters.





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Patients' Rights Charters: Southern Europe

- Cyprus, Greece, Portugal and Spain = Signed and Ratified.
- France and Italy = Signed, not yet Ratified.
- Malta = Not Signed, nor Ratified.
- There is currently one country in Southern Europe that is reevaluating its Patients' Rights.





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Patients' Rights Charters in Southern Europe - A Focus on Children

- Cyprus, France, Greece, Malta, Portugal and Spain, any information on minors' rights.
- Cyprus, Greece, Malta, Portugal and Spain had information on the informed consent.
- No information was found on the right to information about ones own health.
- Cyprus and France had information on the right to access to ones medical file.



Children's Participation in Research

- We currently have answers to the following question from 17 countries.
- 'Do your national regulations allow research on healthy volunteer children (subjects under 16)'?

Austria	Yes	The Netherlands	Yes
Croatia	No	Poland	Yes
Cyprus	No	Portugal	No
Czech Republic	No	Russia	No
France	Yes	Slovak Republic	Yes
Germany	No	Sweden	Yes
Greece	No	Switzerland	Yes
Iceland	Yes	United Kingdom	No
Italy	No		

Appendix- Abbreviations

North-Western Europe

- Belgium: BE
- Finland: FI
- Luxembourg: LU
- Netherlands: NL
- Sweden: SE
- United Kingdom: UK
- Denmark: DK
- Ireland: IE
- Austria: AT
- Germany: DE

Southern Europe

- Cyprus: CY
- Greece: GR
- Portugal: PT
- Spain: ES
- France: FR
- Italy: IT
- Malta: MT

Central and Eastern Europe

- Bulgaria: BG
- Czech Republic: CZ
- Hungary: HU
- Lithuania: LT
- Romania: RO
- Slovakia: SK
- Slovenia: SI
- Estonia: EE
- Latvia: LV
- Poland: PL

● = Countries Under Change

Key Words

- Ombudsman: a person, often a government official who investigates complaints made by citizens against an institution, the government or its functionaries.
- Charter: A document issued by a sovereign, legislature, or other authority, defining the privileges and purposes of i.e. a city.



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European Network of Patients Partnering in Clinical Research (ENPCR)

- Patients/ Patient Organisations may join the ENPCR online forum during the breaks throughout the two day workshop.





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Charters of Patients' Rights

Thank you!!

