

Patients' rights in the European Union: from recognition to implementation

Focus on rights relevant to the cross-border care Directive

A banner for an EPF Roundtable. The background is orange with a stylized map of Europe and green dots connected by lines. The text is in white and blue.

EPF
European Patients' Forum
ROUNDTABLE
On the Implementation of Patients' Rights
In Cross-Border Healthcare
4 December, 9.00-16.30
Thon Hotel EU, Brussels #Patients4CBHC

Willy Palm, Senior Advisor

The logo for the European Observatory on Health Systems and Policies, featuring a stylized yellow and blue graphic of a pen nib or arrow pointing right.

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2017

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Slovenia

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Patients' Rights in the European Union Mapping eXercise (PRE-MaX - 2015)

Rationale:

- “a **mapping exercise of existing patients' rights in 30 countries** (EU28 + Norway and Iceland). This study provides an overview of the various legal frameworks as well as other policy **tools and mechanisms in place** (or in the making) **to define, implement and enforce patients' rights**”
- Potential of developing a comprehensive list of useful and achievable patients' rights?



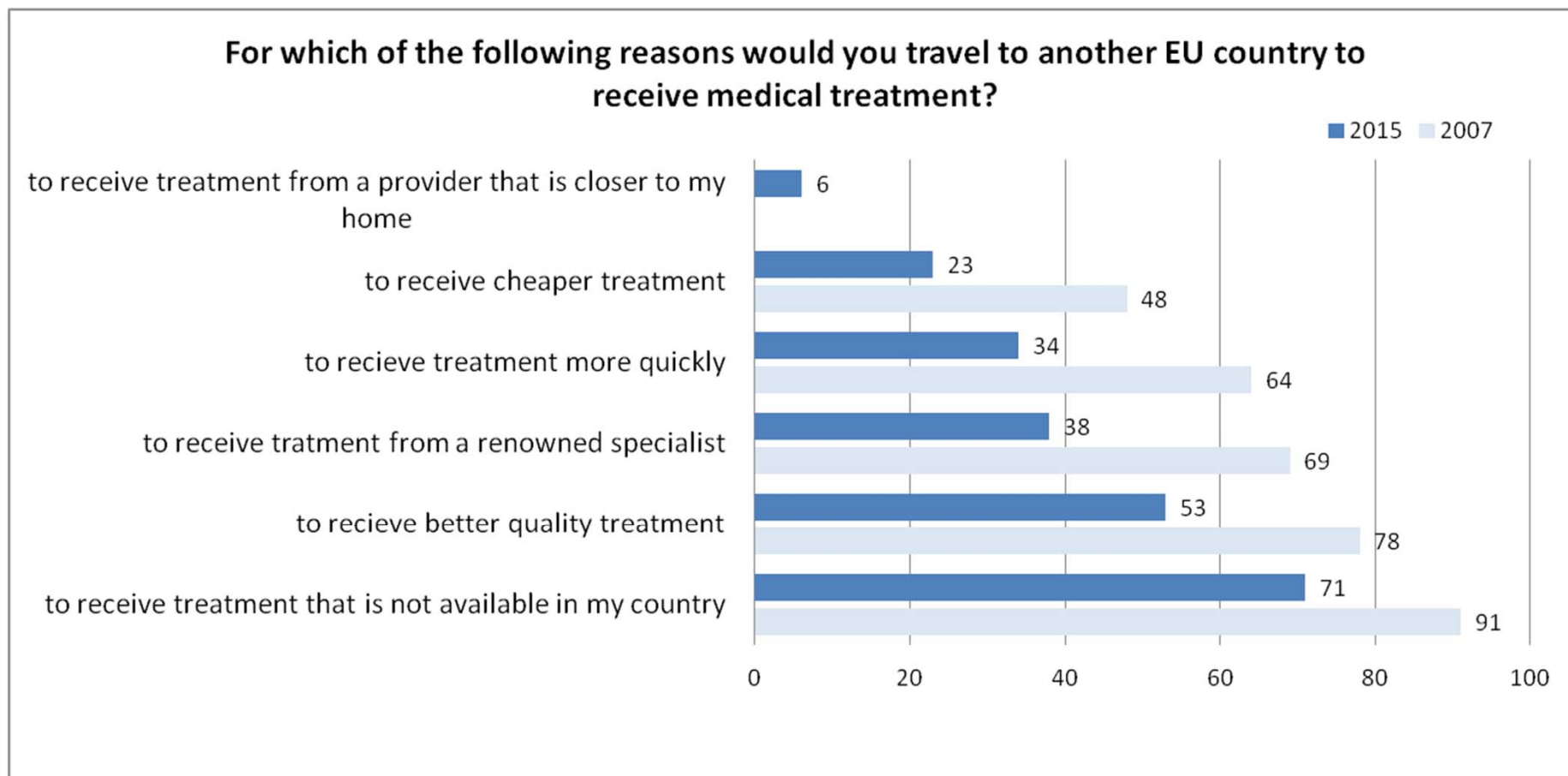
Funded by the European Commission in the frame of the EU Health Programme 2014-2020



#crossborderhealth #Patients4CBHC @OBSHealth @willypalm



Cross-border care and patients' rights?



Source: Eurobarometer 2015 and 2007



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Patients' rights development

Stumbling blocks

- Low sensitivity
- Poor knowledge
- Paternalistic doctor-patient model
- Resistance from the medical profession
 - fear for rise in legal disputes and liability claims, also leading to increased costs due to defensive medicine



Enablers

- Human rights' movement
- Development of health law as a discipline
- Political transition and civil society
- **International framework**
- Increased media attention
- Increased attention for patient involvement and empowerment, quality and safety, medical liability





International framework promoting the development of (general) patients' rights

	WHO (1994)	CoE (1997)	ACN (2002)	EU (2011)
Respect, dignity, integrity	X	X	X	
Non-discrimination	X			X
Privacy, data protection	X	X	X	X
Self-determination, informed consent	X	X	X	
Informed choice			X	X
Access	X	X	X	X
Quality	X	X	X	X
Complaint and remedy		X	X	X
Representation	X		X	



National codification of patients' rights

	Legal (horizontal)		Quasi-legal	Moral
	"Sui generis" private contracts	Generic private contracts	Vertical/public	
Special	Netherlands (1994) Estonia (2001) Lithuania (2001) Slovakia (2004)	Hungary (1997) Belgium (2002) Spain (2002) Poland (2009) Latvia (2010) Czech Republic (2011) Germany (2013) Luxembourg (2014)	Finland (1992) Iceland (1997) Norway (1999) France (2002) Romania (2003) Croatia (2004) Greece (2005) Slovenia (2008) Cyprus (2005) Portugal (2014) Denmark (2014) Sweden (2015)	Austria (2002) United Kingdom (2009) Ireland (2012) Malta (2016)
Split	Bulgaria - Italy			

Updated - Based on H Nys and T Goffin (2010)





Enforcement: the weak link!

- From declared principles to enforceable rights!
a toothless tiger?
- **Enforcement = information + monitoring + dispute settlement**
 - Better knowledge and awareness
 - Increased (compliance) monitoring
 - Internationally
 - Nationally
 - Dispute settlement: Often effective sanctions are lacking for breaches of patients' rights
 - medical liability often still the main instrument to enforce patients' rights





Patients' rights strands

How do they apply in a cross-border care context?



Basic

- **Informed** consent
- Privacy and confidentiality
- Access to medical record
- **Complain and redress**



Social

- Access to health care
- Equal treatment
- **Information**
- **Complain and redress**



Consumer-orienteed

- Shared decision making
- Quality and safety
- Provider choice
- Second opinion
- **Information**
- **Complain and redress**



Life - Health - Dignity - Integrity - Self-determination – Equity - Transparency



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Directive 2011/24/EU on the application of patients' rights in cross-border health care

What patients' rights types do we find in the Directive?



Legal certainty about rights and entitlements to care in another Member State

- Conditions for reimbursement of cross-border health care (benefit basket, level, formalities)
- Prior authorisation (scope, undue delay, administrative procedures)
- Guarantees of information and equal treatment (prices)



Access to safe and high-quality cross-border healthcare

- Information on applicable quality and safety standards and on available providers
- Access to medical record
- Guarantees of non-discrimination, complaints and compensation, professional liability, data protection

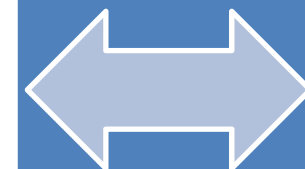


Cooperation on healthcare between Member States

- Basic duty of mutual assistance and cooperation
- Mutual recognition of medical prescriptions
- Areas of cooperation: European reference networks, Rare diseases, e-health, Health technology assessment, border regions



National
Contact
Points





Dual system for reimbursement of XB-care

<i>Procedure</i>	Directive 24/11	Regulation 883/04
Reimbursement level and conditions	MS of affiliation (MSoA)	MS of treatment (MSoT)
Prior authorisation (PA)	<i>(exception)</i> <i>(necessary + proportional)</i> hospital and highly specialised care (art. 8)	<i>(rule)</i> All treatments, except care during stay (EHIC)
PA cannot be refused	When undue delay	When undue delay (*)
Qualifying providers	All providers	Only public or statutorily contracted providers
Third party payer system	No (optional)	Yes

Based on R. Baeten, OSE

(*) Priority if conditions are met
unless patient requests otherwise



Conditions for reimbursement under Directive 2011/24/EU

Prior authorisation				Lower reimbursement rate	Domestic referral
always	No list or not well defined	Clearly defined list	never		
CY	AT, BE, BG, DE, DK, EL, ES, FR, IE, IT, LU, PL, SI	HR, HU, LV, MT, PT, RO, SK, UK	CZ, EE, FI, LT, NL, SW	AT, DE, FI, NL	IE, MT, IT, EE, LT, LV, RO, SK, SI, PL

Source: analysis based on information from National Contact Points' websites (February 2015)





Self-determination and confidentiality

- Informed consent and privacy in general strong protection
- However ...
 - Basic consent before admission
 - No information on alternative treatment options
 - Outdated concept? ‘Informed request’
 - right to participate in clinical decision-making only in some countries formally recognised
 - Neglect and violation of privacy and confidentiality of certain groups
 - Unsafe data processing
 - Access to medical record

- Generally no specific provisions for XBC
- Language support to guarantee informed consent
- Common single consent model
- e-copy of medical file
- Patient and discharge summaries (minimum data set)
- Minimum security requirements to ensure an equivalent level of protection of personal data across the EU





Informed choice of provider and options

- **Choice** of provider often restricted by regulation and reality
 - specialised care (gatekeeping), rural and remote areas, higher user charges for extended choice, public vs private patients = source of inequity
 - **Second opinion:** least formally recognised
 - **Information** on providers: clear and coherent regulation is often still lacking
 - reliable and systematic information on performance most wanted but least available
 - Variation in information duty of providers
 - Centralised public reporting based on different indicators
- Clear information about referral requirements
 - Distinction public (contracted) – private providers
 - Second opinion in another Member State
 - Access to relevant information on providers (including performance, waiting times)
 - Information about border region access arrangements
 - Language?





Quality and Safety standards

- Obligation of the provider to adhere to the standard of care
 - Broadly described, implementation spread over various institutions
 - Ensured through licensing, professional standards, clinical guidelines and protocols
 - Mostly framed as patients' right in case of inflicted harm: fault-based vs non-fault-based compensation systems
 - Timeliness: variation in practice (standardised maximum waiting times (DK, NL), Individual assessment, extended choice for patients beyond max waiting times)
- Accessible information on applied standards
- Providers who raise quality and safety concerns?
- Definition “undue delay”
- Information about waiting times by national contact points
- Redress and compensation: proof and expectations?
- Access to complaint and mediation mechanisms





Conclusions



- Towards an integrated and broad definition of patients' rights.
- They become more widely accepted and more firmly established in countries but national variation in definition, approaches and practice.
- Enforcement is the weak link but progress is made with increased awareness, better monitoring and alternative dispute resolution.
- EU Patients' rights Directive contributes to the development and implementation of patients' rights at national level (also for domestic patients!)
- **Still very difficult for patients to understand and enforce their entitlements to and rights in cross-border care!**



Thank you!

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