

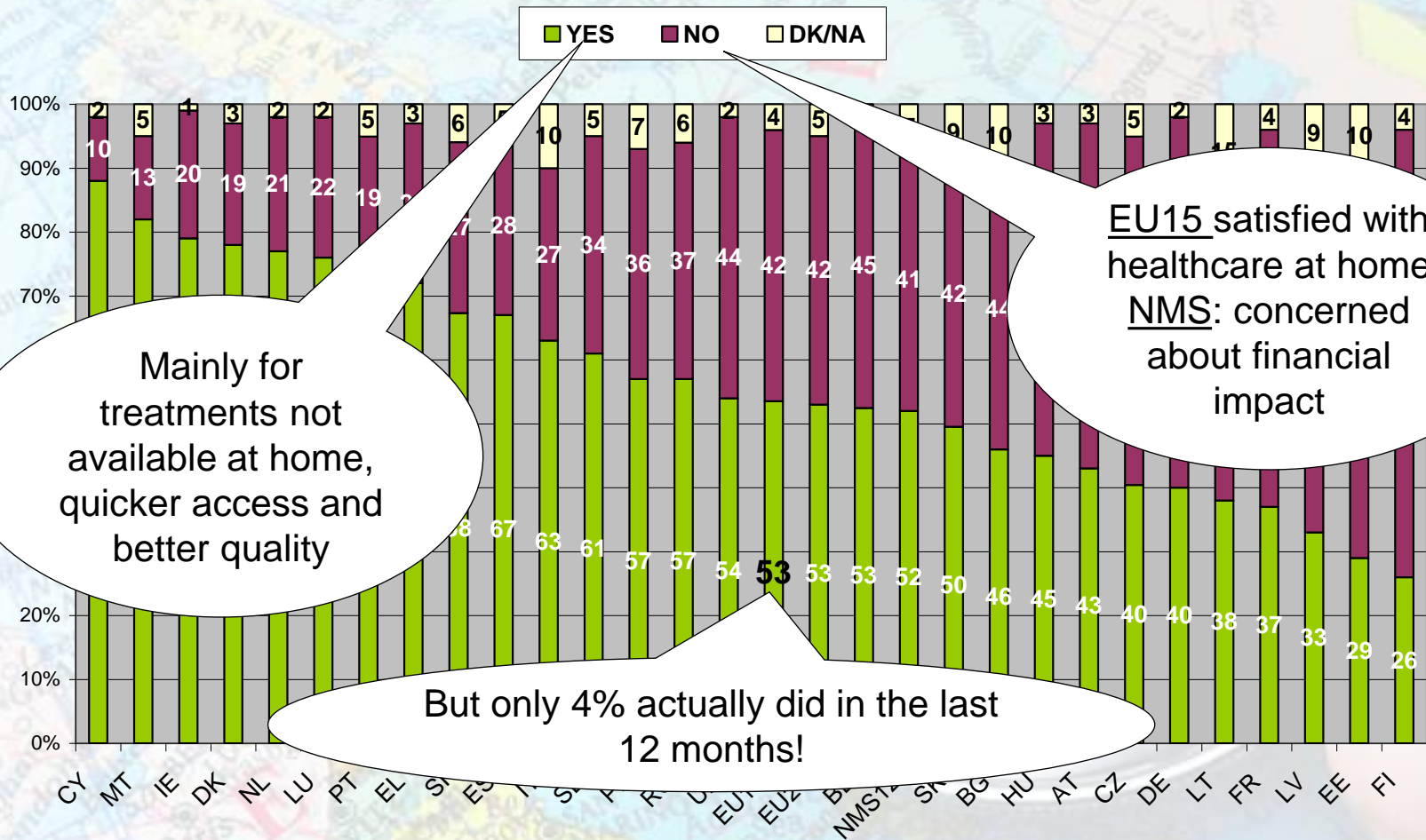
Implications of the Patients' rights directive in cross border healthcare

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Overview

- Patientmobility
 - some (soft) facts
 - Incentives and uncertainties
- The directive
 - The case law
 - The legal provision
- Implications
 - Reimbursement
 - National contacts points
 - Recognition of prescriptions issued in another Member State
 - European reference network
 - eHealth
 - Cooperation on health technology assessment
- Some reflections

Would you be willing to travel to another EU country to receive medical treatment?



Mainly for treatments not available at home, quicker access and better quality

EU15 satisfied with healthcare at home
NMS: concerned about financial impact

But only 4% actually did in the last 12 months!

Source: Eurobarometer 2007

Coordination of social security entitlements

Cost of cross-border care per capita



Average cost/habitant	1989	1993	1997	1998	2004
	€	€	€	€	€
Austria	-	-	0,48	1.87	8.90
Belgium	3,62	8,93	8,93	4.38	6.42
Switzerland					10.02
Germany	1,77	1,83	2,08	2.21	1.87
Spain	0,33	1,48	1,03	1.11	3.72
France	0,79	1,87	1,21	1.05	5.79
Greece	0,95	2,51	2,68	3.15	0.79
Italy	2,99	8,36	3,52	2.89	2.26
Luxembourg	58,01	149,55	135,29	116.0	130.33
Netherlands	1,95	0,26	1,98	2.85	2.63
Portugal	0,82	3,76	6,81	7.00	3.85
Slovenia					0.99
Sweden	-	-	0,65	0.96	1.92
UK	0,33	1,61	1,92	0.36	0.76
Total	1,31	2,95	2,37	1.99	2.74

Reports of the Administrative Commission for social security for migrant workers, 1990, 1994, 1998, 1999, 2005

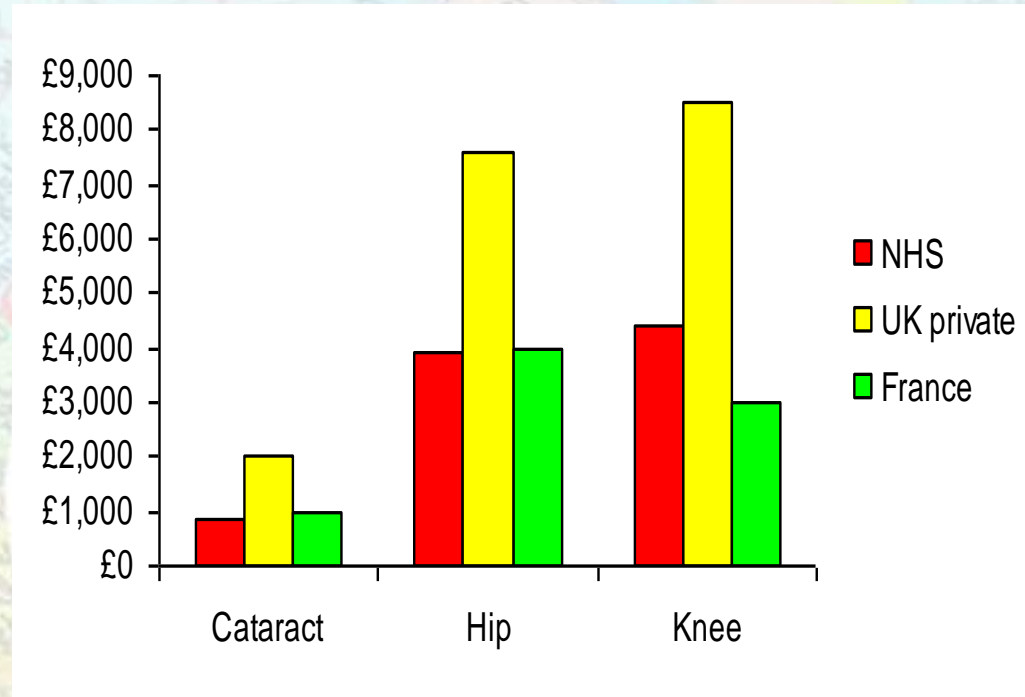
Main focus for cross-border care

- Smaller countries / Border regions
- High mobility areas (tourist zones) / Pensioners
- Rare diseases and high-tech services (reference centers and networks)
- Long waiting times
- Treatments with high user charges (e.g. dental care)
- Well-informed and mobile citizens
- Ethically controversial treatments
- Telemedicine

Role of price differentials?



The first nine patients sent to France by the English NHS (not shown: the 40 journalists who accompanied them)



**ARE THESE DATA REALISTIC?
ARE THEY REPRESENTATIVE?
HOW CAN THE DIFFERENCE BY EXPLAINED?**

The Directive on the application of patients' rights in cross-border healthcare Milestones 1998-2012

1998	First rulings Kohll & Decker	2006	Exclusion of health services from the Services Directive
2001	Smits-Peerbooms rulings		Watts ruling
2002	Revision of the sickness benefits chapter of Reg. 1408/71 on social security coordination		Council Statement on common values and principles in EU health systems
2003	Müller-Fauré/van Riet ruling	2007	EP report on the impact of the exclusion of health services from the Services Directive
	Report on the application of internal market rules to health services		Consultation process on Community action on health services
	High level reflection process on patient mobility and healthcare developments in the EU	2008	Adoption of the new proposal by the College of Commissioners
2004	Commission proposal on services in the internal market	2009	Adoption of implementing Reg. 987/09 on social security coordination
	Creation of the high level group on health services and medical care		First reading in EP
	Adoption of Reg. 883/04 on social security coordination	2010	Monti Report on Single Market Commission/France ruling
	Introduction of the European Health Insurance Card		Council adopts common position
2005	EP Report on patient mobility		Second reading in EP
2006	Commission draft Regulation implementing Reg. 883/04	2011	Adoption of the Patients' rights Directive

Selected topics included in the directive

- Responsibilities of authorities of the Member State of treatment
- Health care provided in another Member State
- Non-hospital care
- Hospital and specialized care
- Procedural guarantees regarding the use of health care in another Member State
- Information for patients concerning the use of health care in another Member State
- Applicable rules on health care provided in another Member State

Selected topics included in the directive

- Duty of cooperation
- Recognition of prescriptions issued in another Member State
- European reference networks
- E-health
- Cooperation on management of new health technologies

Cross-border care and social security coordination (Regulations 883/04 and 987/09)

Modernised
coordination
since 1 May 2010



- People becoming «patients» when abroad (occasional care)
 - Care becoming necessary on medical grounds during a temporary stay taking into account nature of the benefits and expected length of stay
 - Incl. chronic care while abroad (e.g. LT residents)
- Patients crossing for care (planned care)
 - Convenience (proximity, familiarity)
 - Dissatisfaction with or deficiencies in home state system
 - Guided by external (f)actors (health tourism, attractive prices, internet, referral, contract)
- Limitations
 - Many practical problems (distinction between planned and occasional care, application limited to public/contracted providers, acceptance of the EHI card, additional payments if tariffs are higher in home state, etc.)
 - Member States generally maintain restrictive authorisation policies

Prior authorisation
required - E112

« From Kohll & Decker to Watts ...» (ECJ 1998-2010)

- C-120/95 (*Decker*) and C-158/96 (*Kohll*)
- C-368/98 (*Vanbraekelel*)
- C-157/99 (*Geraets-Smits and Peerbooms*)
- C-385/99 (*Müller-Fauré and Van Riet*)
- C-326/00 (*Ioannidis*)
- C-56/01 (*Inizan*)
- C-496/01 (*Commission/France*)
- C-08/02 (*Leichtle*)
- C-145/03 (*Keller*)
- C-372/04 (*Watts*)
- C-466/04 (*Acereda Herrera*)
- C-444/05 (*Stamatelaki*)
- C-211/08 (*Commission/Spain*)
- C-512/08 (*Commission/France*)
- C-173/09 (*Elchinov*)



Directive on the application of patients' rights in cross-border healthcare

Aims

- Provide more legal certainty about rights and entitlements to care in another Member State
- Facilitate access to safe and high-quality cross-border healthcare
- Promote cooperation on healthcare between Member States
- *(In full respect of the national competencies in organising and delivering healthcare)*

Legislative process

- Proposal by the Commission (July 2008)
- Co-decision procedure
 - Revised draft adopted by the European Parliament (1st reading: April 2009)
 - EU Council Presidencies
 - France (2008)
 - Czech Republic (2009)
 - Sweden (2009)
 - Spain (2010): common position (June)
 - Belgium (2010)
 - Hungary (2011)

« old » and « new » patient rights in cross-border healthcare

Social protection (MS of affiliation)

- right to reimbursement of (planned) treatment abroad
 - *As if treatment was received at home (country of affiliation)*
- Alternative to the social security coordination Regulations 883/04 and 987/09
 - *As if the person was insured in the country of treatment*
 - Priority if conditions are met
 - Care is part of the benefit basket
 - Care cannot be delivered within medically justifiable time-limits (undue delay)



Consumer protection (MS of treatment)

- Common operating principles (and structures to support them) that citizens would expect to find in any health system in the EU
 - Quality and safety standards
 - Informed (consumer) choice
 - Redress mechanisms and complaint procedures
 - Liability insurance or similar
 - Privacy and data confidentiality
 - Access to personal medical record
 - Non-discrimination

Implications reimbursement of cross-border treatment

- What healthcare?
 - services (excl. LTcare, organs, vaccination) provided by a health professional to assess / maintain / restore health
 - Provided or prescribed in a MS other than the MSoA
 - among the benefits to which the insured person is entitled in the MSoA
- What patients?
 - Persons insured under a social security or public health system
- What conditions?
 - Up to the level of costs that would have been assumed if it had been provided in the MSoA (without exceeding actual costs)
 - No price discrimination (same scale of fees)!
 - Same conditions, eligibility criteria, regulatory and administrative formalities apply (if not discriminatory and justified by planning requirements to ensure access or contain costs and avoid waste)
 - Prior authorisation only allowed for
 - care subject to planning involving hospital accommodation or use of highly specialised or cost-intensive medical infrastructure or equipment
 - treatments involving a particular risk for the patient or the population
 - providers raising serious concerns relating to quality and safety

So what about private (non-contracted) care and provider choice?

Implications national contact points



- Role of national contact points
 - In treatment state: Q&S standards and guidelines, providers (right to practice), patient rights, redress mechanisms and complaints procedures
 - In affiliation state: rights and entitlements to cross-border care, incl. procedures
 - Language?
 - Collaboration and exchange
- Role of providers (informed choice):
 - treatment options, availability, quality and safety, prices/invoices, authorisation-registration status, professional liability insurance
 - Not more than for domestic patients
- Patients acting as informed consumers (choice, information) will push for performance assessment and comparison (independent broker?)
- What about information for policy-making?

Implications national contact points

- Where to put it?
 - New or existing institutions/organization
 - Ministry or arms-length body or sickness fund?
- How to integrating
 - Fragmentation of data holder
- Information depth
- Information quality
- Adequacy of information for patients

Recognition of prescriptions issued in another Member State

- Verify the authenticity
 - Guidelines for inter-operability of e-prescriptions
 - correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another
 - Comprehensible information to patients
- (some measures to be adopted 25 Oct 2012, others 25 Dec 2012)

European Reference Networks

- development of European reference networks between healthcare providers and centres of expertise in the Member States,
- in particular in the area of rare diseases
- voluntary participation by its members
- Characteristics

Different concepts - focus - motivations

- Centers of excellence
- Centers of reference
- Centers of expertise



- Networks of centers of reference



- Reference networks

Moving/referring patients



Moving/sharing expertise

- Sharing resources (cost-effectiveness)
- Concentrating cases (safety)
- Integrating / standardizing care (quality)

European reference networks

Focus, procedures and tools

- Rare diseases;
- chronic conditions
- highly specialised care
- Specialised hospital functions
- Cancer;
- tertiary care
- Transplants,
- Complex diseases; cystic fibrosis
- burns and trauma care
- diabetes, HIV-AIDS
- National plans
- Contracts
- Accreditation
- Min service volumes
- National rare disease center
- Regionally and nationally commissioned

eHealth

- Commission's implementing decision (22 Dec 2011)
- Establishing a network of national responsible authorities on eHealth

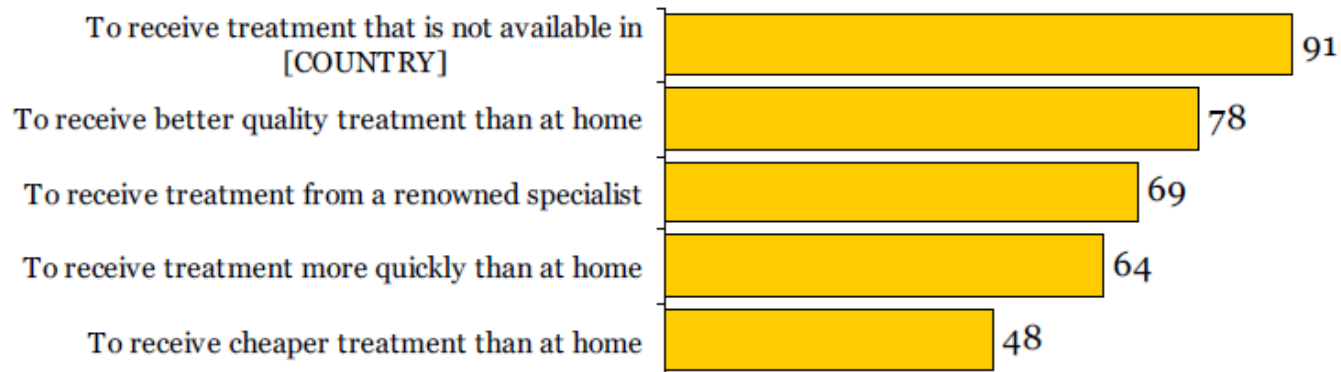
Cooperation on health technology assessment

- EUnetHTA: established to create an effective and sustainable network for health technology assessment (HTA)
- EUnetHTA Joint Action 2010-12
 - Development of a general strategy and a business model for sustainable European collaboration on HTA
 - Development of HTA tools and methods
 - 34 government appointed organisations from 23 EU-EEA member states
- Public consultation on the modalities of stakeholder consultation in the voluntary Health Technology Assessment network to be established under Directive 2011/24/EU (2 May until 1 August 2012)

Some reflections

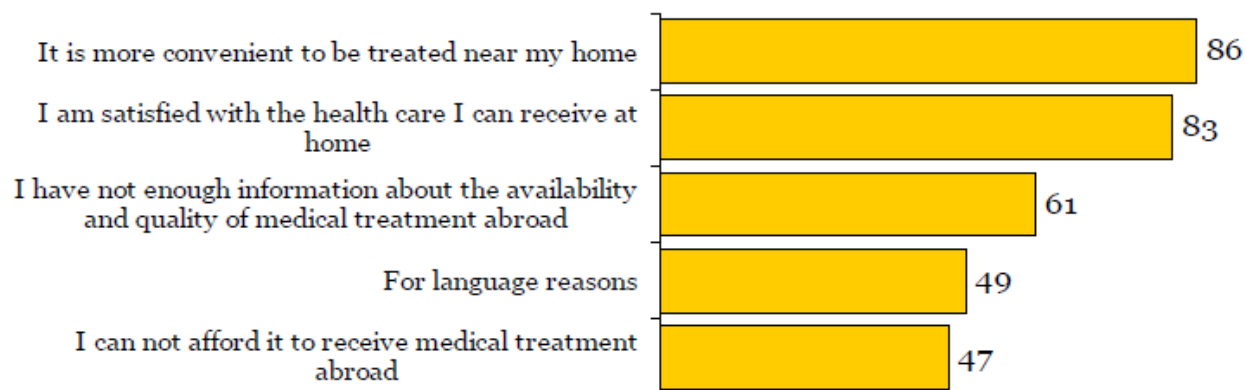
- Implementation is ongoing work
 - More evidence on the situation in Europe
 - Towards solutions
- Some of the legal provisions have already been adopted by the Member States
 - But are they also systematically applied?
- National contact points require a particular effort by Member States
- The implication will have repercussions on health systems in Member states

For which of the following reasons would you travel to another EU country to receive medical treatment?



For which of the following reasons would you travel to another EU country to receive medical treatment?
(Base: % those who would be willing to travel to another EU country to receive medical treatment) % of "Yes"

For which of the following reasons would you not travel to another EU country to receive medical treatment?



For which of the following reasons would you travel to another EU country to receive medical treatment?
Base: % those who would be not willing to travel to another EU country to receive medical treatment % of "Yes"

The importance of cooperation



- Basic duty of mutual assistance and cooperation
 - Quality and safety
 - National contact points
 - Border regions
- Specific areas:
 - Mutual recognition of medical prescription
 - European reference networks
 - Rare diseases
 - e-health
 - Health technology assessment (HTA)
 - (Data collection and monitoring)