The Directive on Patients' Rights and Challenges for Implementation

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Perugia, 10 May 2013

Structure

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4 Practical Impact

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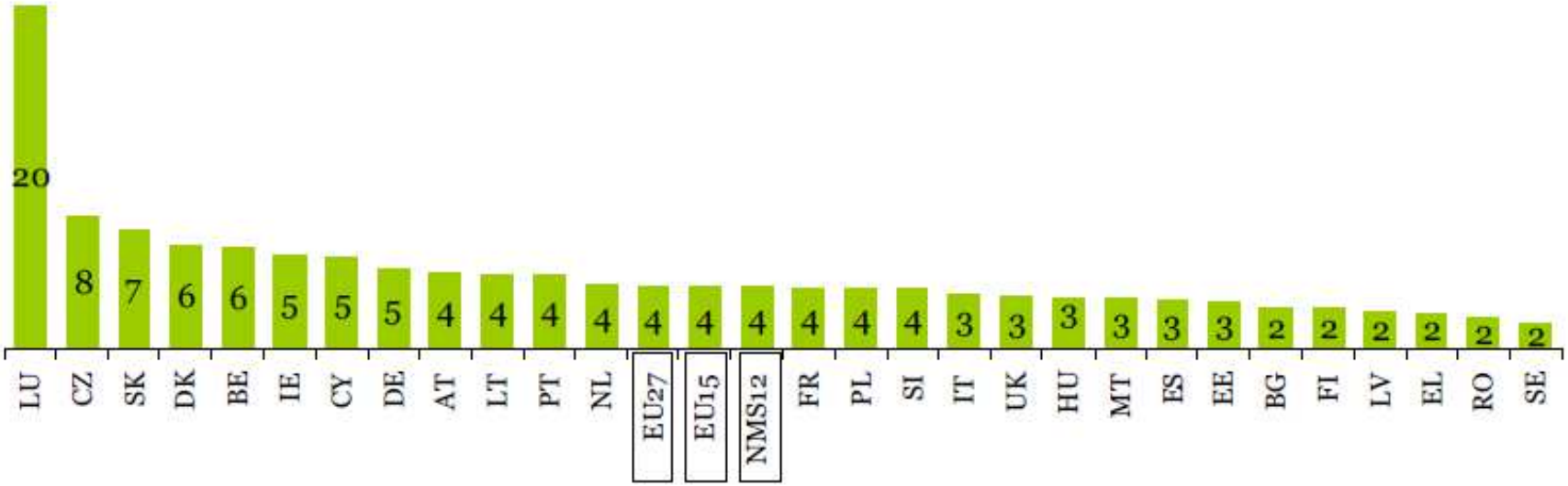
Cross-border Healthcare Experience in the EU

Q2. Have you, yourself, received any medical treatment in another EU Member State in the last 12 months?



Q2. Have you, yourself, received any medical treatment in another EU Member State in the last 12 months?
% yes, Base: all respondents, by country

- Source: Eurostat 2007

Overview of ECJ Rulings I

- Directive 1408/71 (new 883/2004):
  - *EU citizens have a right to emergency treatment (EHIC)*
  - *Planned treatment with prior authorization (E112)*

- ECJ cases go beyond these possibilities

- 1998: Kohll-Decker rulings: Luxemburg, orthodontic treatment in Germany (Kohll) and spectacles from Belgium (Decker):

  Planned ambulatory care EU wide, home tariff reimbursed

- 2001: Vanbraekel / Smits-Peerbooms: Belgium/Netherlands, orthopedic treatment in France (waiting time) / Parkinson treatment in Austria

  Reimbursement for inpatient care, prior-authorization, medical necessity

Overview ECJ Rulings II

- 2003: Müller-Fauré / Van Riet: Netherlands

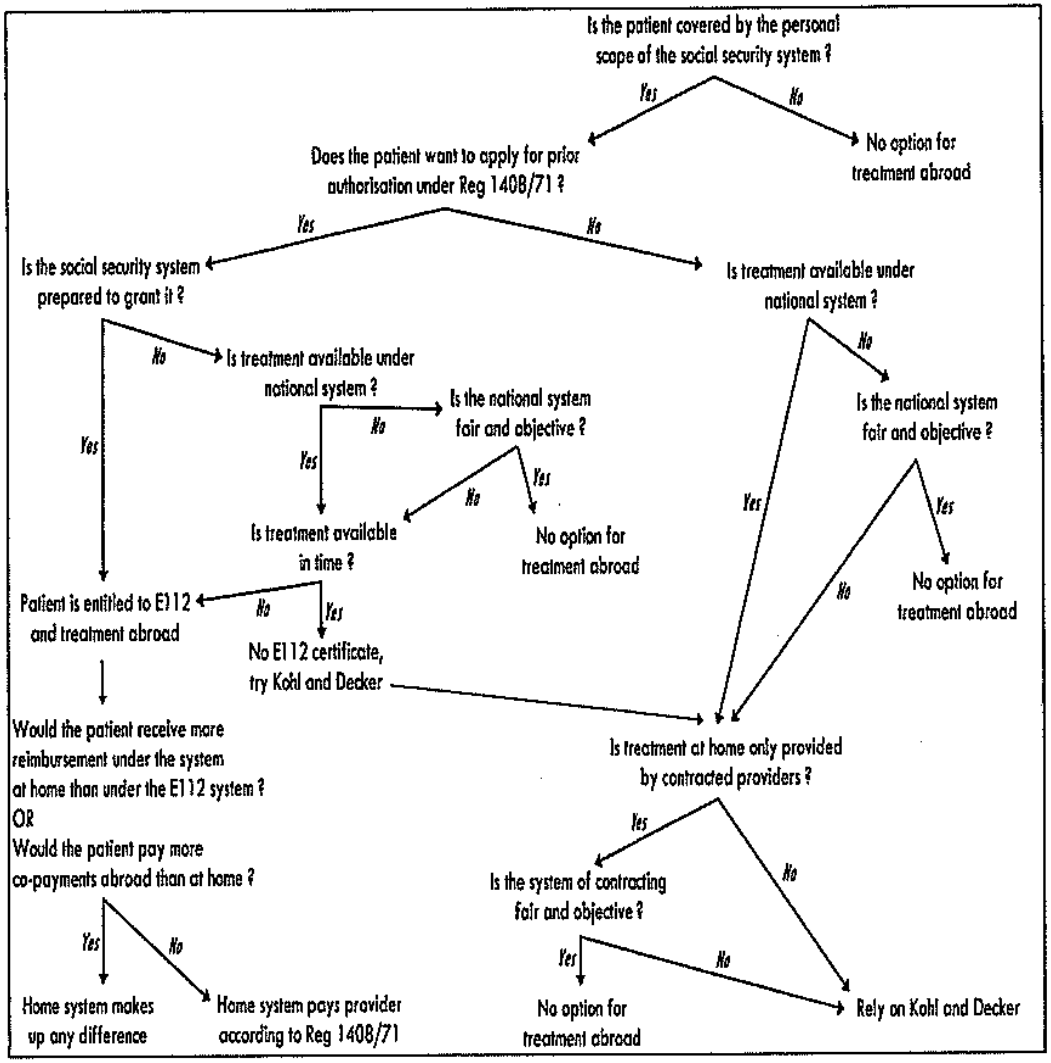
  Confirmation of Prior authorization for hospital treatment

- 2006: Watts: UK, hip replacement in France

  "Undue Delay" and application to NHS systems

- General concerns of Member States and potential impact :
  - potential loss of national control over patients / definition of illness
  - non discrimination of healthcare providers (quality)
  - Lack of definition (medical necessity, undue delay, inpatient/outpatient care)
  - Lack of information
  - Financial problems: viability of national control mechanisms

The system of the Rulings and Regulation 1408/71 (883/2004)



- Source: Nickless(2002), p. 78

Necessity of a Codification

- Various forms of implementation and non-implementation of ECJ rulings
- Negotiations of the Directive proved to be quite difficult, took several years
- Failed attempt of insertion in “Bolkestein” Directive (2005/2006)
- Member State views differed considerably:

  Belgium, Netherlands and Sweden in favour

  Eastern countries and smaller states against

  Many Member States for clarification of definition (EU-wide vs. national)
- Need to create legal certainty for Member States and patients

The Directive on Patients' Rights

- 2007: First proposal, withdrawn by Commission
- 2008: New Directive proposal
- 2009: Failure of negotiations
- 2011: Passing of Directive 2011/24/EU (***transposition till 25/10/13; April 2013: only one MS has drafted a transposition law***)

- *Result*:
- Directive of 21 pages, with 64 recitals trying to clarify the aims and limits of the Directive
- Chapter 1: General Provisions
- **Chapter 2: Responsibilities of Member States**
- **Chapter 3: Reimbursement of Costs**
- Chapter 4: Cooperation in Healthcare
- Chapter 5: Implementing Provisions

Key Points of the Directive I

- ***Overall, the Directive codifies the rulings and thus clarifies their application in all Member States***
  - ***delineation hospital / ambulatory care***
  - ***Obligation for objective and clear prior authorization procedure***
  - ***Criteria for refusal of prior authorization***
- ***Chapter 1: General Provisions***
- Definition of healthcare, Member State of affiliation, Member State of treatment

Key Points of the Directive I ct'd

- **Chapter 2: Responsibilities of Member States**
- **Information and contact points**

- National Contact Points must provide information

- The Member State of treatment must inform foreign patients about quality standards applied to providers (Art. 4.2°)

- Providers must inform patients with all "relevant information" to make an informed choice

- Providers are not obliged to give more information to foreign patients than they do nationally (Art. 4.2°b)

Challenges for Implementation I (a)

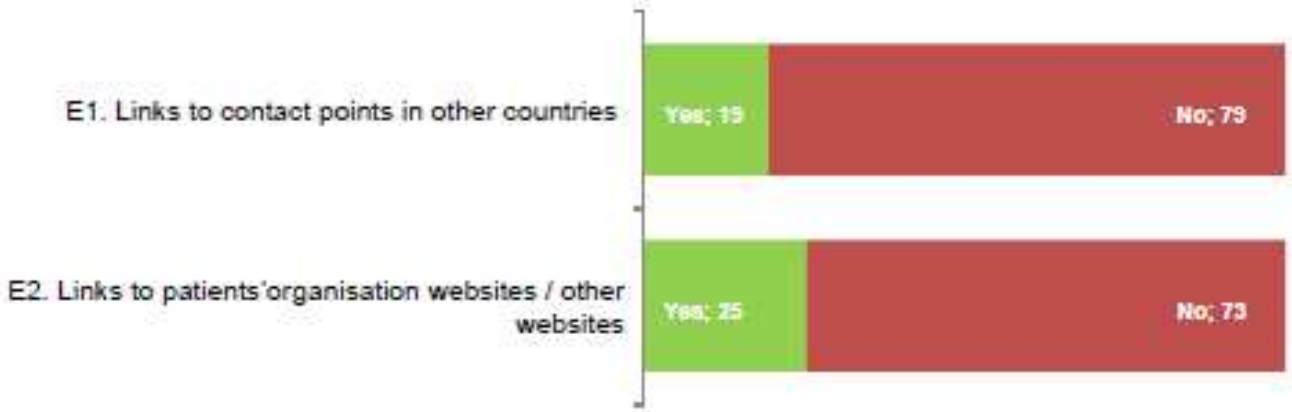
- ***Information points and content of information***
  - One the most difficult issues for implementation of the Directive
  - Large difference between MS regarding available information
  - Fragmentation of nationally available data
  - Where? (central or regional; existing or new institution)
  - What kind of information? Translation issues?
  - How much information? Liability?
  - Adequacy of information for patients
  - Objectivity of information by providers (“informed choice”)?

Challenges for Implementation I(b)

- ***Available information (online)***
- Recommendation Report on websites by PWC (for European Commission)
- Scanned nationally available websites on healthcare in 27 MS (98 websites)
- Source: PWC Report, p. 77:

E. Contact details of NCPs in other Member States

154 The extent to which Contact details of NCPs in other Member States are present on the 98 scanned websites is shown in the figure below.



Key Points of the Directive II

- ***Chapter 3: Reimbursement of Cross-border healthcare***
- Member State of affiliation must reimburse costs for cross-border treatment if the treatment is among the benefits at home (without prejudice to Regulation 883/2004) (Art. 7.7°), exception: hospital treatment
- But MS of affiliation may impose the same conditions and formalities as for the healthcare on its own territory
- Limits: overriding goals of general interest (planning, waste of resources)
- Member States must ensure that providers apply same tariffs for foreign patients as for home patients (Art. 4.4°) and provide clear invoices (Art. 4.2°)

Challenges for Implementation II

- **Reimbursement requirements**
- How to issue a bill to a foreign insurance fund?
- Reimbursement also available to private providers: inequality for those who stay at home?
- What kind of invoices would be acceptable?
- (Hidden) Supplements by private providers? Creative billing?
- Problematic calculation of costs for some hospital treatments (inclusion of tax financed costs / infrastructure…)

Key Points of the Directive III

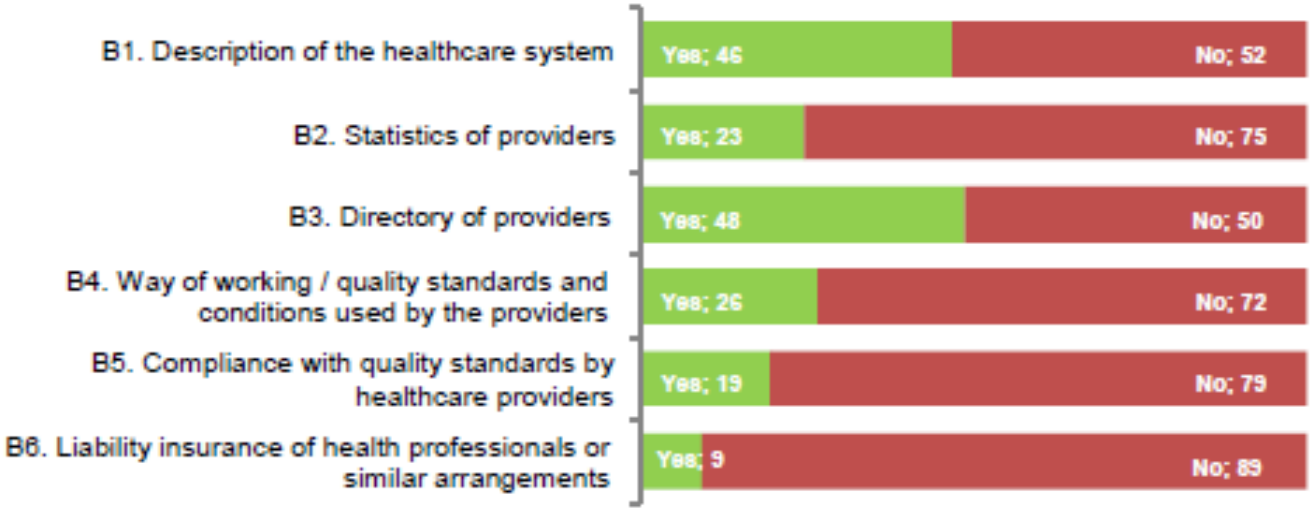
- ***Chapter 3: Prior authorization procedures***
- Treatment in another MS that is subject to prior authorization (Art. 8), list of treatments must be made publicly available
- Includes also treatment
  - that needs an overnight stay (hospital) or
  - involves cost-intensive medical infrastructure or
  - Involves a risk for the patient or the population
  - Provided by a provider who gives rise to quality concerns
- Refusal possible: treatment possible at home (medically justifiable), concerns on standards/quality
- Art. 9: Procedure must be objective and non-discriminatory, individual

Challenges for Implementation III

- ***Prior authorization procedure***
- Who should check quality and security abroad?
- How to check quality abroad of a provider?
- Figures from PWC Report, p. 73:

B. Healthcare providers

136 **The extent to which the information about Healthcare providers is present on the 98 scanned websites is shown in the figure below.**



Further elements of the Directive…

- ***Dual existence with Regulation 883/2004***
  - Test still necessary if Regulation or Directive applies
- ***Obligation of Member State cooperation***
- ***Inflow control is possible (measures must be proportionate and necessary)***
- ***Creation of European Reference Networks***
- ***Acceptance of Prescriptions***

Practical impact

- ***Practical Simulation of the Implementation in Nov. 2011, organized by OSE, EHMA and AIM in Brussels***
- ***Results (Baeten, Jelfs 2012):***
- Patients will most probably always apply for prior authorization to be on the “safe side”
- Rules on quality and safety checks might not be applied
- Burden of proof for invoices will be on the patient (providers don’t want to adapt their bills to foreign insurers)
- Patients rather expect advice than “information” / Insurers reluctant on information regarding quality abroad

Conclusion

- ***Directive codifies ECJ rulings and clarifies several points:***
  - Duties of Member States
  - Criteria for authorization procedure
  - Difference between ambulatory care and hospital/inpatient care etc.
  - Criteria for control on reimbursement, inflow control
- ***Adds new aspects***
  - Information rights
  - Duty of Cooperation between States
- ***Implementation issues remain significant (information, reimbursement requirements)***
- ***Impact for patients ? Impact for systems?***