European Reference Networks

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

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Directive 2011/24/EU of patients' rights in cross-border healthcare

focussing on patients' rights & healthcare across the Union:

- Right to choose and be reimbursed, under certain circumstances for, healthcare provided by public or private providers located in the EU.

- More transparency about their rights, treatment options or, the quality and safety levels of healthcare providers

- Strong focus on cooperation among Member States:

Entry into force at National level 25 October 2013
European Reference Networks (ERN): aim of Article 12:
(Directive Patient's Rights to Cross border Healthcare)

- Support the development of European Reference Networks
- Improving access to highly specialised healthcare for patients suffering of diseases and conditions:
  - low prevalence/rare
  - complex and cost-intensive
  - requiring a particular concentration of expertise
Milestones and timeline for the implementation (ERN)

Delegated Acts (Art. 17)

- Adoption of a list of criteria and conditions for the CR & ERN to fulfil Art. 12.5

Implementing acts (Art. 16) Committee

- Exchange of information and expertise for ERN Art. 12.4(c)
- Criteria for establishing and evaluating ERN Art. 12.4(b)

Deployment Process

Establishment of ERNs

2011 - 2015
Work on progress:
Last steps

Looking at best practices: MS and Centres visits

Meetings with Stakeholders

Meetings with
- EUCERD
- JA Against Cancer
- PARENT

Cross-border Healthcare
Expert Group

SANCO

Draft Delegated
Decision

Draft Implementing
Decision

Commission Inter Services Consultation

Vote in MS Cross border Committee

Adoption of Delegated Decision

Adoption of Implementing Decision

Technical Brainstorming & workshops

Public Consultation

Reports and technical papers

Advise

Legislation
8 objectives of the Directive

6 Areas to be ensured as provided in Article 12 (4) (a)

Criteria supplemented by the delegated act.
Mandate to the Commission (Article 12 (4) (a) and 12 (5))

• 6 sets of Criteria for Networks
• 5 sets of general criteria for Centres
• 2 sets of specific criteria for Centres
Criteria and conditions for Networks

✓ 1. A.1.- have **knowledge and expertise to diagnose, follow-up and manage patients** with evidence of good outcomes

✓ 1.A.2.- Follow a **multi-disciplinary approach**

✓ 1.A.3.- Offer a high level of expertise and have the capacity to **produce good practice guidelines** and to **implement outcome measures and quality control**

✓ 1.A.4.- Make a contribution to **research**

✓ 1.A.5.- Organise teaching and **training** activities

✓ 1.A.6.- **Collaborate** closely with other centres of expertise and networks at national and international level

**Facilitate:** **cost-effective use** of resources

**Focusing on:** highly specialised healthcare / treatment recognised by international medical science (safety, value and positive clinical outcomes)
General criteria for all Members in an ERN (several sub-criteria for each criteria)

(a) patients empowerment and centred care
(b) organisational, management and business continuity of the healthcare provider
(c) research and training capacity
(d) exchange of expertise, information systems and e-health tools
(e) expertise, good practice, quality, patients safety and evaluation

Specific Criteria for the Members adapted to the scope of the Network (area of expertise, disease or condition)

(a) competence, experience and outcomes of care
(b) specific human structural and equipment resources and organisation

Based on the evidence and consensus of the scientific, technical and professional community
Implementation of the Networks

Main principles agreed with Member States

1. **Clear and solid eligibility criteria of the Networks**
2. **Key role of Member States: endorsement and approval**
3. **Participation: voluntary and commitments with the rules.**
4. **Transparency and efficiency of the process**
5. **Based on a strong independent technical assessment**
European Reference Networks LOGO

✓ 1 common logo for all European Reference Networks & Members

✓ The European Reference Networks’ logo constitutes the visual identity of the Networks and its Members.

✓ Registered trademark

✓ Each designated Member will be granted to use the logo according to fixed clear rules

✓ Name of the Network and Member will be included at one side of the common logo (concrete font, colours, position etc.)
The **Commission shall facilitate** the exchange of information and expertise in relation to the establishment of the Networks and their evaluation by

- **Publishing information (website)**
  - establishment and evaluation of the Networks
  - list of the Networks and of their Members
- **Organising conferences and expert meetings**
- **Offering electronic media and communication tools**
March 2014: Adoption legal acts
II Quarter 2014: Call for Assessment Manual
IV Quarter 2014: Selection independent body(ies)
I Quarter 2015: Call for Networks
IV Quarter 2015: Establishment of Networks
Benefits and incentives for Healthcare providers

1. *Improve their experience*, knowledge and capacity

2. *International recognition and visual identity* (quality, expertise and prestige)

3. *Leadership* in their area of expertise

4. *Better capacity and stronger position* to participate in other financially supported alternatives (grants, etc.)

- Health Program 2014-2020
- RTD horizon 2020
- Erasmus + adult learning
- Structural funds

- Clinical trials
- Health Technology Assessment
- Industry
Examples

Pilot networks of cooperation under Directive 2011/24/EU (Public Health WP 2013)

✓ Network of Pediatric Oncology Centers dealing with low prevalence and rare solid tumors
  • EXPO-r-NeT, European Expert Pediatric Oncology Reference Network for Diagnostics and Treatment was awarded with the grant

✓ Network of complex neurologic diseases- Refractory Epilepsy
  • E-Pilepsy
Challenges

- To engage, attract, identify and designate the right Networks and Healthcare providers (the added value)

- To establish a network model with useful platforms and tools

- To have a stronger engagement of MS to ensure sustainability

- To avoid fragmentation / duplication of efforts (too many networks addressing similar conditions)

- To develop and use standardised tools (Clinical Guidelines, registries, patient pathways, interoperability of IT systems, ..)

- To increase the capacity of healthcare providers by the "real" exchange of knowledge and cooperation (virtual tumour boards, etc..)

- To strength the "partnership" between Experts, Scientific Societies, National authorities and EU institutions
Questions to UEMS

✓ Will it be possible to identify domains and groups of diseases / conditions / technologies which will:

✓ Have a clear added value at EU level

✓ Represent a clear need of cooperation due:
  ✓ the scarcity of knowledge and the need of education
  ✓ Low prevalence and rarity
  ✓ Complexity and high cost

✓ Will it be feasible to have a multidisciplinary approach integrating different specialities and areas of knowledge in the same networks
Thank you!

Further information: