



UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES EUROPEAN UNION OF MEDICAL SPECIALISTS

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Discussion paper on European Reference Networks

UEMS Meeting with European Scientific Societies

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Background

European Reference Networks (ERNs) were introduced by Directive 2011/24/EU on patients' rights in cross-border healthcare (Article 12). This document provides for background information as well as food for thought as to how professional organisations, such as the UEMS, can contribute to establishing and sustaining such Networks. It is considered that this can be best achieved through strengthened partnership with Scientific Societies.

General context

All health systems in the European Union seek to provide high quality and cost effective healthcare. This is particularly difficult to achieve for patients who have conditions requiring a concentration of resources or expertise, even more so for those suffering from rare diseases, as expertise is scarce.

Co-operation in healthcare between Member States has increased following the development of EU health policy, even though such co-operation is mainly based on bilateral agreements or common projects in specific fields. In addition, a certain number of networks were already established and supported through the EU Health and Research Programmes in particular in the area of rare diseases, paediatric cancer and neurological complex diseases.

Establishing ERNs bringing together highly specialised healthcare providers in different Member States represents a clear added value for the EU and will help to provide affordable, high-quality and cost-effective healthcare to patients with conditions requiring a particular concentration of resources or expertise. This will also improve patients' access to the best possible expertise and care available in the EU for their condition. Expected benefits are improvements in services delivery, working systems, patient pathways, clinical tools and earlier adoption of scientific evidence. ERNs could also be focal points for medical training and research, information dissemination and evaluation.

This is why Directive 2011/24/EU provides for co-operation in the specific areas where the economies of scale of co-ordinated action between all Member States can bring significant added value to national health systems.

ERNs potential added value

The objectives of the ERNs as set out in the Directive are seen best achievable at EU level. These encompass: European co-operation on highly specialised healthcare, pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, helping Member States with insufficient number of patients to provide highly specialised care. ERNs will also help to maximise the speed and scale of diffusion of innovations in medical science and health technologies.

Accessibility to high quality and safe healthcare for patients suffering from certain diseases varies across the EU and in particular in conditions that require a high concentration of resources and expertise. More efficient and coordinated sharing of resources and expertise would therefore benefit patients and healthcare systems by reducing differences in the quality and outcomes of the healthcare.

Highly specialised healthcare generally requires significant investments in human and technical resources and structures that need to be developed through dynamic and continuous updating of knowledge and technologies. Albeit informal in most cases, many ERNs already were established. Such co-operations were encouraged by the medical profession but need increased support, particularly from the EU.

Participation of healthcare providers in the ERNs is voluntary and requires their acceptance of the criteria and rules for assessing and evaluating them. The purpose is not necessarily to create new care centres but to link existing ones, and/or recognise existing networks.

Whilst most Member States have already invested in centres with well recognised expertise in certain complex procedure(s) or treatment(s), they still lack expertise in other fields of medicine, where centres in other Member States might excel. These disparities and heterogeneity have important consequences in a number of low prevalence diseases and translate into inequalities in access to care within the EU.

Each Member State is competent for the financing, organisation and management of its healthcare system and dependant on its own resources, infrastructure and know-how. There is no permanent platform at EU level to construct partnerships on healthcare and to take advantage of their potential synergies and economies of scale. Such partnerships would enhance the mobility of expertise and produce benefits for patients, professionals, managers and healthcare authorities. The challenge on how to articulate subsidiary role of Member States and EU action.

Legal provisions

Directive 2011/24/EU requires the Commission to support the development of ERNs by adopting a list of criteria and conditions that the ERNs must fulfil as well as the conditions and criteria required from healthcare providers wishing to become a Member of a ERN.

This will be achieved through adopting (1) a delegated act listing the criteria and conditions that healthcare providers and the ERNs should fulfil, and (2) an implementing act containing criteria for establishing and evaluating ERNs, including the exchange and dissemination of information about the ERNs.

The role for the UEMS, professional and Scientific Societies

Together with Scientific Societies, the UEMS can provide for a platform for consultation that could identify a list of diseases or medical conditions that could benefit from ERN cooperation. Centres and experts should then be consulted in order to identify the disease's specific criteria and test the feasibility of these as it is likely that these differ according to the condition at stake.

Depending on the material support that can be attracted, the implementation process should also involve:

1. Convening an interdisciplinary expert group that would first work on top-level conditions and criteria, then would coordinate elaboration of more specialized standards,
2. Organising a voluntary professional accreditation programme for ERNs.

ANNEX – Summary of the key features provided by Directive 2011/24/EC on patients' rights in cross-border healthcare (Article 12)

1. ERNs should be **developed by Member States** with the support of the Commission.
2. ERNs should connect centres of expertise and healthcare providers, particularly in the area of low prevalence, complex or **rare diseases**.
3. Participation to ERNs should be **voluntary and open** to new providers.
4. Objectives of ERNs :
 - a. Exploit medical and scientific **innovations** through EU co-operation
 - b. Improve knowledge on **prevention**
 - c. Improve **diagnosis and delivery** of care
 - d. Maximize **cost-efficiency**
 - e. Reinforce **research** and provide **training**
 - f. Ensure **mobility of expertise**
 - g. Develop **quality & safety** benchmarks
 - h. Receive **patients** from Member States unable to cope with the diseases at stake
5. The Commission is mandated to
 - a. develop the conditions to be met by ERNs and by Healthcare providers wishing to join these. These criteria will include:
 - i. *“have knowledge and expertise to diagnose, follow-up and manage patients with evidence of good outcomes, as far as applicable”*
 - ii. *“follow a multi-disciplinary approach”*
 - iii. *“offer a high level of expertise and have the capacity to produce good practice guidelines and to implement outcome measures and quality control”*
 - iv. *“make a contribution to research”*
 - v. *“organize teaching and training activities”*

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- vi. *“collaborate closely with other centres of expertise and networks at national and international level”*
 - b. develop criteria for establishing and evaluating ERNs
 - c. facilitate the exchange of information and expertise in this regard
 - d. The Commission will do so by means of delegated acts and will have to report on implementation of these provision by 25.10.2015 and every 3 years thereafter.
6. In doing so, any decision **will not harmonize** national laws and regulations and shall respect the subsidiarity principle in the organization and delivery of care.