DEVELOPING **REFERENCE NETWORKS** FOR EUROPE: MOVING PATIENTS OR KNOWLEDGE?

By: Willy Palm, Irene A. Glinos and Bernd Rechel

Summary: After more than ten years of heated debate a European directive was finally adopted in March 2011 that established a legal framework for cross-border health care within the European Union. In addition to setting out rules for providing and reimbursing cross-border health care, the Directive also aims to promote cooperation between Member States, including through the development of European reference networks. With less than one year until the entry into force of the Directive in October 2013, the European Commission is preparing criteria and conditions for such reference networks.

Keywords: *Cross-border Health Care, Cooperation, Reference Centres and Networks, EU Law, Specialised Care, Rare Diseases*

Willy Palm is Dissemination Development Officer and **Irene A. Glinos** is Researcher at the European Observatory on Heath Systems and Policies, Brussels, Belgium. **Bernd Rechel** is Senior Researcher at the European Observatory on Heath Systems and Policies, London School of Hygiene and Tropical Medicine, UK. Email: wpa@obs.euro.who.int

An old idea, a broad concept

The idea of creating – or rather identifying – centres of clinical excellence in Europe was already raised many years ago when the phenomenon of patient mobility started to make its way onto the EU health agenda. It was not only seen as an interesting avenue for developing a conscious, proactive policy towards cross-border care but also as a way of saving costs and improving quality for complex medical interventions or indications by sharing resources between Member States.[1] In an era of increasing clinical specialisation, hospitals were also self-proclaiming their excellence in specific areas to extend their catchment areas, even beyond national borders.

In 2003, the High Level Reflection Process (HLRP) on patient mobility and health care developments in the European Union (EU) recommended that existing initiatives be mapped and their scope further explored, along with the use of cohesion and structural funds. Not surprisingly, the first policy initiatives were taken in the field of rare diseases. It was the Task Force on Rare Diseases that produced the first overview in 2005 and defined a range of criteria that centres of reference should comply with to obtain European recognition. This was followed by various pilot projects on specific rare diseases, which received financial support under the EU's public health or research framework programmes.[2]

To some extent, the initial focus on rare diseases contributed to another significant development: the gradual shift from identifying individual European centres of reference (ECRs), which, based on their specific equipment and/or expertise could treat patients from all over Europe, towards the creation of European reference

networks (ERNs) which would connect different centres to share knowledge and expertise in diagnosing and treating complex cases. This accommodated the idea that the EU, rather than organising the mobility of patients through labelling expert centres, should instead promote mobility of knowledge and information.

> Improve access to highly specialised care

Despite these developments, the concept of European reference networks (or centres) was never meant to be restricted to the particular area of rare diseases nor was it focused entirely on moving knowledge instead of patients. The HLRP noted that any system of ECRs should be flexible, objective, transparent and leave choices as to its use open to the responsible authorities. Even if the EU promoted the idea that expertise rather than patients should travel, it was recognised that both aspects could not – and should not – be dissociated from each other. Partners within the networks, by disseminating information and developing guidelines on state-of-the-art treatment for specific conditions, would particularly attract patients from countries where this expertise is lacking.

European reference networks under the Directive

The concept of ERNs as specified under the Cross-border Care Directive[3] follows this broad approach. In its preamble, the Directive suggests that "all patients who have conditions requiring a particular concentration of resources or expertise" could benefit from providers networking to improve access to high-quality and cost-effective care (Recital 54). Cooperation in the field of ERNs and rare diseases is developed in Articles 12 and 13.

Article 12 rather than providing a real definition for the concept of ERNs, lists their objectives and the criteria they should fulfil. It leaves room for different types of networks pursuing different objectives or motivations by specifying a range of eight different objectives of which ERNs need to embody at least three (Article 12.2). Whereas initially the idea of ERNs seemed to be inspired by the objective of improving cost-effectiveness through concentrating resources across borders, it increasingly became motivated by the desire to improve safety and quality through concentrating cases, raising standards and even integrating care. Equity also plays a role, since reference networks might give Member States, whose limited patient numbers or resources make investing in the necessary equipment and infrastructure difficult, access to highly-specialised services for their populations outside of the national territories.

In setting the framework within which the Commission is now requested to define a more detailed list of criteria and conditions for ERNs and providers wishing to join them (Article 12.4), the Directive also applies an open and integrative approach. Rather than exclusively focusing on the clinical excellence that is naturally expected from ERNs in the actual diagnosis and treatment of patients, the Directive recognises that expertise should also be reflected in a broader range of aspects: a multidisciplinary and coordinated approach; special attention to evaluating outcomes and controlling quality; strong links with medical training and research, and an active role in developing standards and best-practice guidelines. In addition, good communication skills and the involvement of patients and patient groups are regarded as key features for recognising reference networks, as well as their willingness to collaborate closely with other centres and networks.

In fact, by focusing on networks rather than centres and by emphasising the multifaceted approach and openness to sharing and collaborating, the Directive avoids the trap of being dragged into a spiral of competition between clinical institutions to become the top reference centre in Europe. On the contrary, networking supports the goals of benchmarking, mutual support and knowledge transfer between Member States and centres in the same clinical field.

Building on national practices

In order to be successful, ERNs need to reflect and build on existing practices in Member States. Although the concept of reference centres and networks is known in most European health care systems, a review of experiences in 20 EU Member States and Norway found substantial variation, not only in the scope and motivations for developing them, but also in their state of progress and political importance.[4]

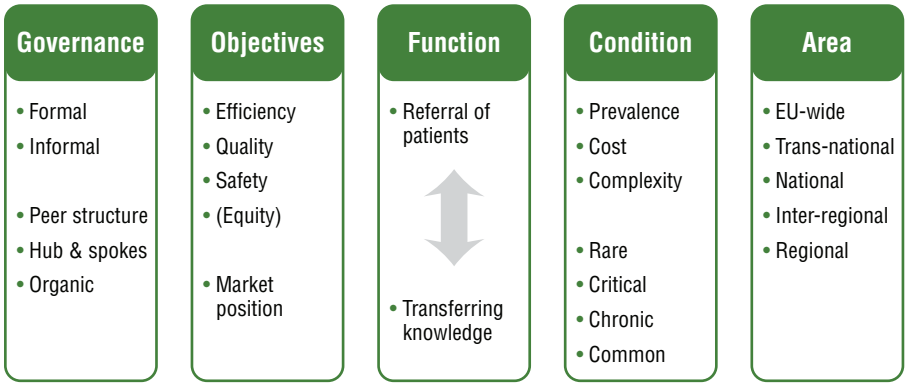
Based on the review five key dimensions can be distinguished in the establishment and functioning of reference centres and networks (**see Figure 1**):

- The way they are organised and governed;
- The purpose or motivation for their development;
- Their function (what they do);
- Their material scope (what type of patients/conditions/care they focus on);
- Their geographical scope.

While several European countries have not yet officially embraced the concept of reference centres or networks, a growing number of countries have in recent years initiated specific regulation and frameworks for establishing reference centres or networks, sometimes under the direct influence of the Cross-border Care Directive. Most often, this was motivated by the need to concentrate the provision of highly specialised services in a limited number of medical institutions. Some countries also have "*de facto*" systems, in which certain hospitals or departments – mostly teaching hospitals – have become the leading centres to which the most complex and severe cases are referred because of their traditional position or recognition among professionals. However, proper referral rules, designation criteria and systematic quality assessment are often lacking.

Gradually, in many countries more formal systems are being set up. Partly due to the

Figure 1: Dimensions to define reference centres and networks



Source: Palm W, Glinos I A, Rechel B, Garel P, Busse R, Figueras J (Eds.) Building European Reference Networks. Exploring concepts and national practices in the EU. Observatory Studies Series 28; (forthcoming 2013).

effects of the financial crisis, countries have stepped up efforts to rationalise and reconfigure hospital care, categorising their hospitals into distinct levels that specify their remit both in geographical terms and in the types of care to be provided. Although the need for a more centralised and structured provision of specialised hospital services is generally justified in view of benefits for efficiency, cost-effectiveness, quality and equity, it sometimes also faces criticism and distrust.

In Central and Eastern European countries, centralisation efforts may evoke memories of the old Shemasko model, which provided only limited choice for patients. In decentralised systems, centralisation may be perceived as an attempt by the central level to gain more control over the health system. In some cases, it is even argued that the designation may actually impede collaboration between hospitals. Whereas such negative perceptions most often come from providers who are questioning or challenging the designation, providers are sometimes also the biggest proponents. Obviously, their interest in the concept may not always be in accordance with health system objectives, but based on more business-oriented motivations and the need to seek a return on investment for highly specialised equipment through consolidating their market positions or even extending their catchment areas. The danger here is that without any clear framework the concept is used to increase patient expectations, as well as the scope and prices of provided services, giving rise to provider-induced demand. Therefore it is important to establish objective, detailed and transparent procedures, with the involvement of all relevant actors.

Some European countries have developed well-established systems and procedures for defining and designating reference centres and networks, as well as for monitoring their activities and outcomes. A good example is Spain. Since 2006 the country has elaborated a joint planning system for concentrating specific specialised services in reference centres, departments and units (RCDUs) of the National Health Service (SNS). Under the supervision of the SNS's Interterritorial Council, a special designation committee, in which the Autonomous Communities and the Ministry of Health are represented,* identifies the priority diseases and procedures for which concentration is desirable. This can be either motivated by the use of very advanced technologies (e.g., total skin electron radiation), the involvement of a high level of specialisation or the low prevalence of cases (rare diseases, transplants). Reference services can only be established for treatments that are part of the publicly funded basket of health care services. With the help of a group of experts the designation criteria are defined for each area of specialisation. The actual selection of RCDUs is made on the basis of centres proposed by the autonomous community governments. Following a qualification process in which each centre is audited by the SNS's Quality Agency, the designation committee proposes the centres for nomination to the Ministry of Health. The designation is awarded for a maximum period of five years. The RCDUs are monitored annually. An information system gathers data on the procedure and the outcome indicators included in the designation criteria.

To date, 46 priority diseases and procedures have been identified and the designation criteria for thirteen areas of specialisation have been defined. Up to 2011, 132 reference centres, departments and units of the SNS had been designated for 35 diseases and procedures. Nearly 90 of them are monitored through the information system. The care provided by the RCDUs is mainly funded through a national cohesion fund.

However, not all approaches to reference networks require a general planning process. Concentration of specialised services and referral of patients can also be achieved through minimum activity thresholds, as for instance applied in Germany, or through special agreements or contracts between statutory health insurance bodies and a range of reference centres that specialise in the treatment of specific rare or chronic diseases, as in the case of Belgium. In addition, quality standards and certification processes can be used as tools to define and impose the level of expertise and multidisciplinary approach that is expected from reference centres and networks for the treatment of rare and complex cases.

For what conditions?

One of the important challenges that EU and national regulators are facing is how to define the scope for reference centres and networks. Similar to the EU policy processes described above, rare diseases are clearly a prime focus for developing the concept of reference centres and networks also at Member State level. Several countries recognise centres for specific rare diseases and have established national networks, often built around a central coordination centre. The Italian National Network for Rare Diseases,

* In Spain, the regions, known as Autonomous Communities, are responsible for managing the regional health system and delivering health care.

established in 2001, is coordinated by the National Centre for Rare Diseases (part of the National Health Institute) and links certified care providers who were mandated by regional authorities. France adopted a National Plan for Rare Diseases in 2004, which included a designation procedure for reference centres for specific or groups of rare diseases. The Czech Republic, Belgium and Malta are developing similar strategies.

Furthermore, in areas of critical and complex conditions similar plans for centralising and networking are being implemented. Examples can be found in the fields of transplants, burns, trauma and stroke care. The concept also has considerable appeal in the field of cancer. Countries are setting up reference centres in oncology, not only to address some rare cancers but also to improve the quality of care and to ensure speedy uptake of new therapies. In some cases, these networks are less focused on the actual provision of care but rather on the idea of sharing knowledge and best practice, as well as the coordination of training and research.

This further extends the scope to chronic conditions (e.g., diabetes) as they can also benefit from this kind of networking. In Germany, the Competence Networks in Medicine, initiated at the end of the 1990s, promote horizontal collaboration between research institutions to stimulate innovative medical therapies in specific areas of disease (e.g., mental health, Parkinson's disease, dementia, specific cancers, rare diseases), as well as vertical integration with medical specialists to accelerate transfer into practice. Another good example are the five Hospital-University Institutes (IHU) in France, a collaboration mechanism between tertiary care hospitals and universities, involving teams of renowned biomedical researchers involved in education and translational research. Smaller interesting examples include the Dutch ParkinsonNet, coordinating regional networks of closely cooperating specialised professionals, and the Alliance for Heredity Issues (VSOP), also in the Netherlands, which is run by organisations of parents and patients with rare, genetic and congenital disorders, aimed at improving care through information, research and patient participation.

> "goals of benchmarking, mutual support and knowledge transfer

This wide variety of national practices illustrates that prevalence of conditions is just one, and not necessarily the most relevant, indicator that justifies the setting up of ERNs. The question of whether there is sufficient critical mass within a country or a region to address rare diseases depends not only on the size of the country (after all, the European definition of rare diseases still results in about 30,000 cases in the UK alone): available expertise and treatment capacity are also highly relevant. Prevalence alone fails to indicate the type of disease; how well established treatment options are; what is required in terms of interventions and support; or whether it involves a short period of treatment or ongoing care.

Next steps

From the national experience, it is clear that also at EU level there are important challenges to ensuring that the various (potentially competing) regional, national and international concerns are reconciled, not least when it comes to selecting the potential centres to be part of the ERNs. In addition to involving national and regional health authorities in reviewing and assessing candidate centres, it is equally important to use detailed and, objective criteria, as well as having good monitoring and information systems in place. Since on some occasions the expertise and willingness to share knowledge can be specifically linked to the presence of certain individual specialists, it is important to perform periodical re-assessments of designated centres and networks. Moreover, given the financial implications that the labelling of centres as part of ERNs may have,[5] it could be important to constrain their scope and expectations and develop a gradual approach in designating European reference networks.

To enable the development of ERNs, the European Commission is required to adopt a Delegated Act that defines the criteria that ERNs and health care providers wishing to join them have to fulfil. To support and advise the Commission, a Cross-border Health Care Expert Group was established with representatives from Member States. In addition, in late November 2012 the Commission launched a public consultation, inviting stakeholders to give their views on the criteria for selecting diseases or conditions suited for creating ERNs, and for determining which centres can join them.[6] In a next phase the Commission will adopt an Implementing Act for establishing and evaluating the ERNs as well as facilitating the exchange of information and expertise.

To come up with a system of criteria that is clear, pertinent and perceived as fair and that can work in 27 different national settings is not an easy task. After all, the difference in Member States' approaches to reference networks and centres is just a reflection of the diversity between health systems in Europe.

References

1 Communication from the Commission. Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union, COM/2004/0301 final, 20 April 2004.

2 See: *Report of the EU Committee of Experts on Rare Diseases (EUCERD),* February 2011.

3 Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, *Official Journal,* 4 April 2011, L88/45–65.

4 Palm W, Glinos I A, Rechel B, Garel P, Busse R, Figueras J (Eds.) *Building European Reference Networks. Exploring concepts and national practices in the EU.* Observatory Studies Series 28, forthcoming 2013.

5 See: Baeten R, Jelfs E. Simulation on the EU cross-border care Directive. *Eurohealth* 2012;18(3)18–20.

6 Public consultation on the implementation of European Reference Networks (ERN) web page. European Commission. Available at: http://ec.europa.eu/health/cross_border_care/consultations/cons_implementation_ern_en.htm