Hearing of the Expert Panel on Effective Ways of Investing in Health

Hearing on "Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases' area"

Brussels, 25 September 2018

Background

The Expert Panel on Health is currently working on an Opinion on the 'Application of the European Reference Network (ERN) model in European cross-border healthcare cooperation outside the rare diseases' area'. Opinions of the Expert Panel are drafted to support the European Commission in identifying specific aspects to be considered as well as tangible results that should be achieved to make a real change in terms of reforms to health systems and investments at the EU level. This hearing was held to gather views from a range of key experts on public health and healthcare services from well known institutions and professional bodies, representatives of Member States, non-governmental organisations, academics, EU institutions and relevant stakeholders from health-related areas (industry, research, economy). The hearing will contribute to shaping the Opinion on 'Application of the European Reference Network (ERN) model in European cross-border healthcare cooperation outside the rare diseases' area' and to provide input for reflection on possible actions to be undertaken at the national and European levels.

Four members of the Expert Panel on Health led the discussions:

Professor Jan De Maeseneer
Professor Sabina Nuti
Professor Walter Ricciardi
Professor Martin McKee

Hearing – introduction to the Expert Panel's Opinion

Following a brief introduction by Martin McKee, the hearing started with Walter Ricciardi setting out key elements of the Opinion before key experts expressed their views on the Opinion. The following is a summary of the key points raised by members of the Expert Panel on Health and the key experts.

In his presentation, Prof. Riccardi set out the key questions covered by the Opinion: Which areas can benefit from the ERN model? Should the ERN model be used to cover training/knowledge creation? How do national health systems integrate such networks?

Since the Maastricht Treaty, the EU has recognised the contribution that cooperation can bring to European citizens. He stressed that there is a principle of voluntary cooperation and that Article 12 of the Cross-border Healthcare Directive established the ERN as a set of virtual health provider networks to facilitate discussion. A key feature of the ERN is that it enables healthcare providers to access a larger pool of expertise and thereby increase their chances of delivering a better diagnosis and ultimately better treatment.

The ERN focusses on different rare diseases. It has been a major success, with over 300 hospitals across the EU being part of it. It was up and running only as of March 2017 and, given that it is a relatively

new concept, there is limited knowledge about it. Two of its major benefits come from pooling medical expertise and pooling patients.

Pooling medical expertise by convening specialists in member centres and by uploading individual patient cases to a Clinical Patient Management System. The coordination of experts on rare diseases has resulted in the development of guidelines, with 39 new ones published by (ERKNET), as well as knowledge sharing and benchmarking.

Pooling patients: creating a critical mass of patients. Collecting and coordinating experience in treating patients with rare conditions requiring complex treatment allows for the development of registries (ERKNET) and provides a platform for research.

The Opinion was based on in-depth interviews with two ERN coordinators. Their suggestions, which the Expert Panel fully shares, included:

Robust and more refined referral mechanisms are needed in national health systems to ensure equitable access for patients;
Adequate funding is needed;
A clear management system and mechanism of governance are needed;
Cost effectiveness is imperative.

Conclusions/recommendations
Setting up ERNs has been among the most important European cooperative initiatives for a decade;
The idea of extending the model to other diseases is premature;
The application of an ERN model will depend on the needs to which the model is expected to respond;
Independent research into ERNs is important;
Training is of key importance.

He also made the following other points:

At the national level some ingredients of what have made the ERNs successful can be used.

Most Member States do not have a coordinating mechanism. The Expert Panel would encourage them to develop such a mechanism for other areas rather than adopting an ERN model.

The Expert Panel would not recommend that Member States use the ERN model to solve the problem of access to care in remote/rural areas but stressed that there are numerous examples of cross-border cooperation that Member States can use.

The Expert Panel does not see the ERN as offering the most appropriate mechanisms to deal with issues such as the homeless/refugees/disaster prevention but would encourage Member States to optimise care for these groups/situations.

The Expert Panel believes that there are alternative mechanisms than the ERN to address the development of new medicines or interventions.

Question and answer session on clarifications

A session of questions and answers for clarification purposes ensued.

Ioanna Psalti, an advisor at the European Glaucoma Society and European Alliance for Vision Research and Ophthalmology, pointed out that there was a lack of awareness about the ERNs. She asked how open the referral system is regarding patients and if the project is open to other submissions.

In response to a question about evaluating the existing ERNs, Prof. McKee said that it is too early to do that. He added that not every Member State has to be in an ERN (as per the principle of subsidiarity) and not every Member State is represented in every ERN and that the ERN is a voluntary grouping of organisations. He stressed that the Commission can facilitate but not impose cooperation.

Ms Psalti asked if, where a Member State is not a member of an ERN, it can submit a patient case to be reviewed.

Prof. McKee's understanding was that it can in that, under EU law, there is no reason why a Member State cannot develop a relationship with another Member State. He noted that there is not sufficient expertise in every Member State to take part in each ERN.

According to Prof. Nuti, a lot of clinicians do not even know about the ERNs and it is therefore difficult to evaluate how the ERN model is working. She noted that, where some countries have a strict way of organising their referral network and the relationship between clinicians and hospitals, other countries do not. She pointed out that, in many countries, it is hard for clinicians to know where they should send their patients.

Prof. McKee pointed out that many Member States are unaware of ERNs and called for stakeholders in the hearing to advertise the role that the EU plays in improving the lives of patients.

Helen Brewer, CODE External Engagement Lead at the European Society of Anaesthesiology, noted that the Expert Panel said that the ERN model does not apply to common diseases and asked if the ERNs could apply to more rare interventions such as allergic reactions in anaesthesia or rare conditions such as malignant hypothermia.

Prof. McKee's response was that, for emergencies such as allergic reactions or malignant hypothermia, the ERN mechanism will not work due to timing issues. He suggested looking at other mechanisms such as via research projects. He added that the Expert Panel is not saying that action should not be taken (e.g. regarding the homeless or civil disasters) but that it is not clear how the ERN mechanism could be used for that purpose.

Stakeholders' views

A session in which stakeholders expressed their views ensued.

Ines Hernando, ERN and Healthcare Director for EURORDIS, was very positive about the report. Speaking on behalf of rare disease patients, whilst she agreed that two main benefits of the ERN were in helping to diagnose patients via the system and in helping to pool health data/expertise, she argued that the ERN should not be limited to that as only the rare cases go there (i.e. a relatively small number of cases) and stressed that the issue of its integration into national health systems is very important. She added that, for patients, guidelines and recommendations for better care are important and not just multidisciplinary but also integrated care guidelines for chronically ill patients. She added that the training of experts is very important as is the potential for training this very small number of experts and that maintaining the capability in the systems and the sustainability of training is critical.

Pascal Garel from the European Hospital and Healthcare Federation was positive about the report. He pointed to difficulties such as with the referral mechanism, integration of national health systems and doctors/other healthcare professionals not being aware of the ERNs and noted that Brexit is one of the key issues in the governance of the ERNs. He has pointed out the issue relating to the governance of the ERN to the European Commission but has not had any answer from any institution.

In terms of expanding the ERNs to disease that are not rare diseases, he acknowledged how complex it has been to deal with rare diseases (e.g. to merge different subgroups of rare diseases together) and agreed with the Expert Panel that it may be too early (and may always be too early) to have the same kind of ERN mechanism for non rare diseases. In the context of non rare diseases, things are happening and can be learnt at the national, local and European level, for example from the European observatory. He concluded that it was a very good report to evaluate the ERN, that it is too early to know what is going to happen and that it is a good way to continue the discussion in future years when this comes back on the EU's agenda.

Prof. Nuti underlined the importance of patient participation and suggested that the Expert Panel could add to the Opinion the idea that ERNs should have public reporting/benchmarking so that the public can know more. She also argued that the communication process – the idea that some people such as clinicians and patients' associations do not know that the Commission is working on this – should be improved.

Ms Hernando said that stakeholders are doing a lot to raise awareness but that they are missing support from Member States. She put this down to the fact that we do not have the evidence and said that we need the evidence so that Member States buy in to it. She stressed that Member States need to do more to raise awareness and agreed that public reporting would help.

Prof. McKee said that the Opinion did not talk about Brexit as it is pointless to speculate before knowing what the cabinet in the UK government wants from Brexit. He urged professional bodies and patient organisations to speak about the advantages of health cooperation across the EU as he has noted that some organisations are reluctant to speak out.

Charissa Frank from bindweefsel.be, who is also a patient advocate, said that her organisation is actively involved in finding health care providers in countries where there are none. She added that they do not always have the appropriate funding to do that because they are a patient organisation and do it in their own free time.

An exchange between Lavinia Meloni from Weber Shandwick, Prof. McKee and Ms Hernando ensued.

In response to one question from Ms Meloni about how Member States will reimburse cross-border healthcare in terms of doctors billing their time across many countries, Prof. McKee said that an EU Directive sets out the mechanisms dealing with that.

A key issue in the exchange was about how hospitals can work with the private sector. Prof. McKee said that this was a matter for Member States, not something that the Commission could have a role in and that modern hospitals engage with the private sector a lot already (e.g. to buy new scanners or pharmaceuticals).

Ms Meloni seemed to want to understand the policy through which the ERNs can engage with external stakeholders.

Ms Hernando seemed to want to know how clinicians can engage with industry to develop clinical trials within the ERN. She also pointed out that funding has come up as a problem for clinicians, that

they are looking outside Member States and the Commission for funding and that they need rules to get industry money into the ERNs.

While Prof. McKee noted that hospitals have rules for engaging with industry, Ms Hernando said that hospitals can do this individually but not as a network. She stressed that hospitals cannot label the result [of clinical trials] as an ERN finding.

Prof. Ricciardi's understanding was that industry wants to use the ERN label as a way to market the results of a clinical trial. He added that the Commission's approach is not to mix public labels with private labels. Even in the planning of the next budget for research, he noted that private and public streams are being discussed. In most countries, he said that there is a reluctance to label private initiatives.

Asked what the benefit for patients is, Ms Hernando said that she wanted clear rules of engagement with industry, as, if there are no rules, it will happen anyway but there will be no transparency on what is going on.

Prof. McKee explained that there is nothing preventing any company from setting up its own network but it cannot call it an ERN.

Ms Hernando said that the ERN has all the experts.

Vinciane Quoidbach from the European Brain Council pointed out that not all countries can take care of all the patients with the rare diseases. She suggested that collaboration could be established between neighbouring countries for clinical trials and also for reimbursement. She suggested that it should be integrated into the expenditure that somehow, for a country to enter into such a collaboration is of added value for the national system. She also said that there is insufficient integration of ERNs into national health systems.

A couple of years ago, countries were invited to adopt policies on rare diseases. She asked if there was some space in research and evaluation for ERNs inside those policies because when we adopt policies at country level, we have to translate those policies into legislation and into particular directives for hospitals and expertise centres.

Prof. McKee suggested that if a country does not have a capacity and the capacity is across the border, that it should use that capacity. Facilities are shared between regions across borders from each other (e.g. between Belgium and France, between Belgium and the Netherlands). He noted that there are a lot of examples where treatment can be shared and that the mechanisms exist. He added that this is not for an ERN to do as ERNs are about referring people for diagnosis.

He argued that Europeans need to be advised of the benefits for their health provided by the EU, suggesting that, for example, many elderly Europeans seem to think that the EU is opposing them even though it is benefiting them.

He also underlined the need to celebrate and advertise the benefits of EU action.

Ms Psalti suggested looking into synergies relating to EU disease registries and how ERNs can create more registries. She also stressed the need for communications channels.

Prof. McKee said that every Member State has a focal point for cross-border healthcare and that there is no reason why hospitals in ERNs should not connect to that. He noted that many registries are funded by the EU and many are not.

Whilst personally, he said that he would advocate a single Europe-wide system for data collection, he noted that this is not possible under the Treaties.

Ms Brewer asked what happens with existing ERNs and how the Opinion impacts them.

Prof. McKee said that that was a question for national governments and MEPs.

Dalma Fabian from FEANTSA, the European Federation of Homeless Organisations, noted a recommendation in the Opinion to set up a learning community to improve access to healthcare for the homeless in Europe, said that this could be useful for FEANTSA's work and asked for a summary of the Working Group's discussions on the homeless.

Prof. McKee lamented the fact that the life expectancy of the homeless was up to 20 years less than those who are not homeless and noted that it is a growing problem in Member States. He could not see the added value of the ERN model here. However, he recognised the problem, expressed sympathy with it and stressed how important it is to raise awareness that people are dying on a large scale because of the inability to build houses in Europe.

Final summary by Prof. McKee

The Opinion is not designed to evaluate the ERNs. ERNs need to be well integrated with national health systems. This is a matter for Member States and not for the Commission.

There is a case for encouraging best practices. There is also a need to advocate discussions in the European health agenda for research (e.g. research on integrating services). It needs to be made clear to research councils that they need to do locally and contextually based research.

We talk about the ERN guidelines in integration registries. This is a lot about Member State responsibilities. ERNs are networks of hospitals. They should be liaising with the focal points of the cross-border healthcare Directive.

The Expert Panel was very immersed in discussions about the legal text and operation of the Directive on cross-border healthcare. It is clear from the questions during the hearing that not everyone is as familiar with it as the Expert Panel is.

It was a very difficult law to get approved but is a strong mechanism for doing the things that speakers today are asking to be done. It is an opportunity for healthcare professionals to make use of it.

Everyone has a responsibility to show that the EU is a powerful force for better health in Europe. He warned that if we as a whole do not do that, we will lose it.

Next steps

The Expert Panel will reconsider comments and incorporate them into the final Opinion.