



# FIRST CONFERENCE ON



# European Reference Networks

**Brussels, June 23 2014**

# REPORT

**Share. Care. Cure.**

# TABLE OF CONTENTS

EXECUTIVE SUMMARY .....	3
INTRODUCTION AND BACKGROUND .....	4
AIM OF CONFERENCE .....	4
NUMBER AND TYPE OF ATTENDEES .....	5
PLENARY SESSION .....	5
Only Connect: What ICT networks can do for society .....	5
Complex Systems and Networks .....	5
FRAMEWORK FOR THE ESTABLISHMENT OF ERNs .....	5
Past, present and future of centres of expertise and European Reference Networks .....	5
The importance of sharing expertise and the challenge to manage the exchange of knowledge in highly specialised healthcare .....	6
Research priorities and networks .....	6
The ERN model: Criteria and conditions for networks and providers. Implementation of networks: organisation framework .....	7
BREAKOUT SESSIONS .....	8
Session A: Highly specialised healthcare for low prevalence, rare and complex diseases .....	8
A1: The view of the stakeholders' organisations .....	8
A2: National models .....	10
A3: Networking Experiences (Network pilots funded by EC .....	12
Session B: Quality, clinical criteria and performance assessment .....	14
B1 Clinical and professional criteria .....	14
B2 Accreditation, certification and evaluation .....	16
CLOSING REMARKS .....	19
CONCLUSIONS AND STEPS FORWARD .....	19
ACKNOWLEDGEMENTS .....	19

## EXECUTIVE SUMMARY

The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare strengthens co-operation between highly specialised healthcare providers across the European Union by the establishment of a system of European Reference Networks (hereinafter ERNs).

Establishing ERNs of highly specialised healthcare providers 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, and to improve these patients' access to the best possible expertise and care available in the EU for their condition.

The legal framework of ERNs adopted by the Commission entered into force on 27 May, after an exhaustive consultation process with national authorities, experts, and stakeholders.

DG SANCO organised this conference to bring together highly specialised healthcare providers, experts, national authorities, decision-makers, and independent bodies with experience in the assessment and evaluation of healthcare providers.

The aim of the conference was to discuss the state of play on the organisation of highly specialised networks and their members across the EU and to look into the next steps of the deployment process, in preparation for the forthcoming call for ERNs in 2015.

The delegated and implementing decisions entered into force in May 2014 and are the present legal framework for ERN and Centres of Expertise (hereinafter CoE).

The delegated decision states the criteria and conditions for providers and networks and the implementing decisions determine how to establish, assess, and evaluate networks and exchange the information among providers.

The main future challenges will be the implementation or establishment procedure (ensuring the compatibility with the criteria laid down in the delegated decision and evaluating providers that want to build up a network) and the sustainability of ERNs and CoE. The latter will be the responsibility of Member States but a solution is still needed to ensure the sustainability of ERNs

Although the Cross Border Healthcare Directive does not foresee any funding for the ERNs and the Commission does not have a specific mandate in this area, some cross-sectorial co-operation and funding sources have nevertheless been identified. So far, these are the Public health programme 2014-2020, RTD horizon 2020, Connecting European Facilities (CEF), Structural funds and Social funds. In any case, the commitment of Member States will be necessary for presenting the projects.

The possibilities technology offers nowadays to connect are clearly immense. One of the biggest powers people have is the power to connect to each other, connect things and connect knowledge.

This is one of the reasons for which the classic model of networks needs to be disrupted; it cannot be conceived the same way as a decade ago. If ERNs want to be successful, they need to go beyond connecting a technocratic elite by making the public part of the problem definition and the solution.

In the area of cancer, ERNs and CoE are key in the light of the increasing specialisation and fragmentation of cancer care, inequality of access to care, and patient demands for high quality care.

Professionals, managers and patients support the initiative but take notice of the challenges each of these groups will face in the implementation process.

On the other hand, the presented national models and pilot projects will hopefully provide a good base of lessons learned for the implementation of ERNs.

Concerning clinical and professional criteria, the German Association of the Scientific Medical Societies Institute of Medical Knowledge-Management gave its view on enhancing medical professionalism, interdisciplinarity and quality of healthcare through clinical practice guideline development.

In addition, NICE gave an overview on the establishment of clinical criteria, including best practices, clinical guidelines and patient pathways. Finally, the Lombardy Cancer Network (hereinafter ROL) exposed their experience in assessing the use of EU clinical guidelines in a network environment and showed how this could be adapted to a European level.

The topic of accreditation, certification and evaluation was covered by the Danish Health and Medicines Authority, the French National Authority for Health, the National Centre for Quality Assessment in Healthcare of Poland and by Accreditation Canada International.

The Danish example shows that centralisation and specialisation has helped to improve the overall quality in the healthcare services and treatments. On the other hand, France brought important insights as one of the biggest and obligatory accreditation systems, whereas Poland focused on the key elements of their voluntary accreditation system.

Accreditation Canada International brought very valuable insights regarding independent assessment and accreditation models.

In terms of milestones and steps forward, the ERN legal acts entered into force in May 2014. The call for the assessment manual took place in July 2014, the call for selection of independent bodies will be made in the fourth quarter of 2014, the call for networks in the fourth quarter of 2015, and the establishment of networks in the second quarter of 2016.

All involved stakeholders are requested to prepare the network proposals during 2014-2015 by identifying the clusters of diseases (ERN scope), qualified healthcare providers and informal networks and by establishing synergies. Then, during 2015 the Commission will produce guidelines and technical documents for the network proposals.

## INTRODUCTION AND BACKGROUND

The welcome address on ERNs given by Dr Andrzej Rys, Director DG SANCO Health Systems, highlighted the background of ERNs.

The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare strengthens co-operation between highly specialised healthcare providers across the European Union by the establishment of a system of ERNs.

Establishing ERNs of highly specialised healthcare providers 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, and to improve these patients' access to the best possible expertise and care available in the EU for their condition.

ERNs for rare diseases should serve as research and knowledge centres, updating and contributing to the latest scientific findings, treating patients from other Member States and ensuring the availability of subsequent treatment facilities where necessary. The definition of ERN should also reflect the need for services and expertise to be distributed across the EU.

In 2005, the Rare Diseases Task Force Working Group on centres of reference submitted its first report to the Commission's High Level Group on Health Services and Medical Care. The report was used to feed a general reflection on the establishment of clinical centres of reference in Europe, based on the example of centres of reference for rare diseases.

In 2006, the Rare Diseases Task Force Working Group on centres of reference submitted its second report on the use of the concept of centres of reference and their functions.

The legal framework of ERNs adopted by the Commission entered into force on 27 May, after an exhaustive consultation process with national authorities, experts, and stakeholders.

## AIM OF CONFERENCE

DG SANCO organised this conference to bring together highly specialised healthcare providers, experts, national authorities, decision-makers, and independent bodies with experience in the assessment and evaluation of healthcare providers.

The aim of the conference is to discuss the state of play on the organisation of highly specialised networks and their members across the EU and to look into the next steps of the deployment process, in preparation for the forthcoming call for ERNs in 2015.

## NUMBER AND TYPE OF ATTENDEES

The conference was well attended by 335 people from 32 countries, of which 13 delegates were participants from non-EU countries. The countries with the most delegates were Belgium (100), Italy (33), United Kingdom (24), France (23), Germany (22), Spain (20), Portugal (14), Slovenia (14), The Netherlands (13), and Sweden (10). Those attending represented a wide range of stakeholders, mainly national institutions or authorities (68 participants), professional or scientific associations (58 participants), healthcare providers in the public sector (46 participants), patient organisations (26 participants), European Commission (21 participants) and healthcare providers in the private sector (18 participants).

## PLENARY SESSION

*Only Connect: What ICT networks can do for society. Mr Robert Madelin; Director-General for DG CONNECT: Communications Networks, Content and Technology*

The possibilities technology gives us nowadays to connect are immense. One of the biggest powers people have is the power to connect to each other, connect things and connect knowledge.

This is one of the reasons for which the classic model of networks needs to be disrupted; it cannot be conceived the same way as a decade ago. If ERNs want to be successful, they need to go beyond connecting a technocratic elite (or guiding people by this elite) by making the public part of the problem definition and the solution.

A successful network nowadays needs to be collaborative among its teams, transparent and inclusive with those outside the network. Also, it would be a big mistake if ERNs stayed in disease-specific silos.

Their duties should be first, reaching out beyond network (for which criteria are necessary) and second, reaching between the networks, since some of the most exciting discoveries might not be identifiable if you only focus on a disease.

Technology and social media are key drivers of a rapidly changing world in which progress is not linear and limits and boundaries are not clear. This change can be seen in the power of computing, the access to this power by anyone and the fact that working with each other has become normal. Also, in this era where computation power provides all the data we want, selecting the data we need and knowing where to look for it is of utmost importance.

Finally, networks should not only respect the rules of research, but have a more fundamental look at fairness and respect in the way we talk to people.

*Complex Systems and Networks. Prof Yamir Moreno; Institute for Biocomputation and Physics of Complex Systems (BIFI); University of Zaragoza*

A complex system is a system made of many non-identical elements, interacting in non-linear ways. The function of the system results from this interaction and is not something that can be understood by studying the isolated components of the system. The importance and complexity of the system come from the interactivity of elements, which is why the backbone of complex systems is networks.

Networks are ubiquitous in nature and everything around us is connected. These networks are made up of nodes and links. One of the most important properties is the connectivity or degree of a particular node, which is the number of other nodes it is linked to, as it measures centrality (the more neighbours you have the more central is your position).

This is why understanding and modelling the structure of complex networks would lead to a better awareness of their dynamic and functional behaviour.

## FRAMEWORK FOR THE ESTABLISHMENT OF ERNS

This roundtable moderated by Dr Paolo G. Casali - Istituto Nazionale Tumori, Italy, focused on highly specialised healthcare, in view of the future framework for the establishment of ERNs.

*Past, present and future of centres of expertise and European Reference Networks. Dr Till Voigtländer; Clinical Institute of Neurology, Medical University of Vienna*

Regarding the legal framework of ERNs and CoE, the latter is laid down in the Council recommendation of 2009 and Member States were requested to develop national plans by the end of 2013 to lay down concepts on how to designate or implement CoE in each country. On the other hand, ERNs are included in article 12 of the Cross-border Healthcare Directive 2011, which states the criteria for all Member States.

From a timeline perspective, the ERNs and CoE started to be developed about ten years ago by Member States and the European Commission. The process behind this was the high-level reflection on patient mobility and healthcare developments (Outcome document 2003 and agreement between Commission and Member States to make this a priority in the public health field).

In the following years several committees were set up and reports published. One should highlight the working group on ERNs and CoE, the Task Force on Rare Diseases (established by the Commission to provide scientific advice), the EUCERD and the CBHD Expert Group, the forum for consultation and advice from the MS to the Commission regarding the elaboration of the delegated and implementing decisions of the CBHD.

These two decisions entered into force in May 2014 and are the present legal framework for ERNs and CoE.

The main future challenges will be the implementation or establishment procedure (ensuring compatibility with the criteria laid down in the delegated decision and evaluating providers that want to build up a network) and the sustainability of ERNs and CoE. The latter will be the responsibility of Member States but a solution is still needed to ensure the sustainability of ERNs.

Regarding feasibility, it is worth mentioning the three pilot reference networks which were successfully established. These networks had different backgrounds and were funded by different sources. What they do have in common is that they provided the proof of concept, evidence and important lessons learned. Second-generation pilot reference networks are at the moment providing evidence that designation can work, finding partners and the operating experience.

*The importance of sharing expertise and the challenge to manage the exchange of knowledge in highly specialised healthcare. Dr Josep Maria Borrás; Partnership for Action Against Cancer (EPAAC)*

EPAAC (2011-2013) involved many partners and one of the main topics was the Health care WP7 aimed at identifying and exchanging best practices. Three of the main objectives focused on building consensus in multidisciplinary cancer care, assessing the networks in cancer care and investigating the feasibility of harmonisation of clinical guidelines in rare tumours at EU level.

Organisation of cancer care matters for prognosis and outcomes of patients in a community because in cancer we need to combine different therapeutic strategies. Diagnostic process is very important, innovation is continuous, and research is very relevant. In this sense, ERNs and CoE are key in the light of the increasing specialisation and fragmentation of cancer care, inequality of access to care, and patient demands for high-quality care.

A network is a cluster of professionals with certain structure, strong clinical leadership, and strategic co-operation that may coexist with competition. It should evaluate clinical outcomes and should develop learning and informational mechanisms. Networks provide a framework for access to expertise.

Relevant aspects to take into account are the management of health professionals according to expertise, mechanisms in place for exchange of information on complex patients, promoting cross-cutting learning mechanisms for experts and clinical accountability for the decisions made.

Finally, harmonising clinical guidelines (CG) on rare cancers is feasible, but the challenge is the implementation of guidelines and evaluation of outcomes. Also, the role of the patient organisations should be strengthened although there are few experiences of this so far.

In conclusion, stakeholders' involvement in relevant cancer care issues is feasible at EU level, as shown in the example of EPAAC. Also, organisational approaches are increasingly relevant in the cancer policy: networks as the best example. Furthermore, efforts should be focused on implementation of clinical guidelines and assessment of clinical outcomes in networks. The main challenges that remain are the implementation and of guidelines and compliance with them, how to reimburse the treatment in networks, external accountability and patient involvement.

*Research priorities and networks. Ms Irene Norstedt and Philippe Cupers; DG RTD*

EU Research Frameworks are the largest supra-national source to fund unique international consortia, public-private partnerships and global co-operation.

Overall FP7 objectives are to improve the health of European citizens, to address global health issues and to boost the competitiveness of European health-related industries. The aim is to carry out top quality research and produce innovations to keep us, our healthcare systems, and our healthcare industry and economy in good condition. This is done through collaborative projects in applied research and innovation and international co-operation, that is to say through connecting researchers.

The projects in the area of rare diseases show the variety of issues that different networks can address. Even networks focusing on one specific disease area, such as cancer, can promote different issues, such as the promotion of clinical trials, determination of biomarkers, registries and biobanks.

The main problem is that all examples are about connecting researchers. However, it is very important to bring industry into the networking. IMI achieves collective intelligence networks, improves R&D productivity of pharma industries and innovative approaches for unmet public health needs. As mentioned in previous talks, one very important challenge is to increase patient involvement, which IMI achieves by involving more than 25 patient organisations as members and direct participants in the projects. Involvement of regulators is also important.

Regarding Horizon 2020, its three pillars are excellent science, industrial leadership and societal challenges. The difference with the FP7 is that the latter was focusing on disease-specific areas and Horizon 2020 does it on innovation in general. It includes 34 healthcare topics, such as understanding health, ageing and disease; effective health promotion, disease prevention, preparedness and screening; improving diagnosis; innovative treatments and technologies; advancing active and healthy ageing; integrated, sustainable, citizen-centred care; improving health information, data exploitation and providing an evidence base for health policies and regulation.

**The ERN model: Criteria and conditions for networks and providers. Implementation of networks: organisation framework. *Dr Enrique Terol; DG SANCO***

Within the legal frame of Directive 2011/24/EU of patients' rights in cross-border healthcare, the main aim of the ERN is to improve quality, safety and access to highly specialised healthcare for patients by focusing on diseases that are very difficult to tackle at national level due to their rarity, low prevalence and complexity.

The delegated decision states the criteria and conditions for providers and networks and the implementing decisions determine how to establish, assess, and evaluate networks and exchange the information among providers.

In the delegated decision there is a set of horizontal criteria and conditions to be fulfilled by all healthcare providers regardless of the field of expertise and a set of specific criteria and conditions that may vary depending on the area of expertise. These criteria should be based on evidence and an agreement of professionals and it should be a bottom-up approach.

Regarding the implementing decision, the four main players are the healthcare providers, SANCO as the facilitator of the system, the Member States and the independent assessment bodies. The Commission will organise a call for networks probably at the end of 2015 and there will also be a continuous system of open applications for providers wishing to join one of the already established networks.

An eligibility check will be followed by a technical check of criteria and conditions. Successful networks will receive the logo and will be evaluated after 5 years, based on which the Member States will confirm or not the continuation of a certain network.

At the moment we are in the communication and awareness phase, informing providers through various means. For this the Commission is working with the key stakeholders. Also, an assessment manual will be prepared, giving legal criteria for an auditor when checking a network. The Commission is organising a competitive call where this manual will be a key element.

Regarding milestones, we have the entry into force of the legal acts in May 2014, the call for the assessment manual in July 2014, the call for selection of independent bodies in the second quarter of 2015, the call for networks in the fourth quarter of 2015, and the establishment of networks in the second quarter of 2016.

All involved stakeholders are asked to prepare the network proposals during 2014-2015 by identifying the clusters of diseases (scope of ERNs), qualified healthcare providers and informal networks and by establishing synergies. Then during 2015 the Commission will produce guidelines and technical documents for the network proposals.

The Cross-Border Healthcare Directive does not foresee any funding for the ERNs and the Commission does not have a mandate here. However, some cross-sectorial co-operation and funding sources that have been identified so far are the Public Health Programme 2014-2020, RTD horizon 2020, Connecting European Facilities (CEF), structural funds, and social funds. The commitment of Member States will be necessary for presenting the projects.

The Public Health Programme will cover the organisation of the call for networks and the process of assessment, auditing and labelling of the networks, including the cost of activities related to the exchange of information on the assessment, evaluation and outcomes of the networks, a number of project grants for approved networks and the development of tools we will need for the networks (communication tools, guiding documents and methodology to develop guidelines, etc.). What seems clear is that a sustainable funding mechanism would depend on the success of the first approved ERNs and on the political decision of the legislators to give a mandate for the financial support of the ERNs.

## Main points of discussion and debate

- Concerning funding, the commitment of Member States and the use of other interesting sources, such as European structural funds, cross-border collaboration funds and transregional collaboration funds are two other mechanisms mainly depending on regions.
- The call for networks is quite flexible as it asks for rare, low prevalence and complex diseases. The number of networks is not defined but it clearly is not feasible to set up networks for all existing diseases.
- In order to make patient organisations an integral part of the network we need to discuss in each of the networks what the best approach is.
- There will not be an accreditation system but an assessment of the fulfilment of the criteria. Then Member States will validate the network based on that.

## BREAKOUT SESSIONS

### Session A: Highly specialised healthcare for low prevalence, rare and complex diseases.

#### A1: The view of the stakeholders' organisations, chaired by Dr Andrzej Rys; Director Health Care Systems, DGSANCO

##### *The view of the professionals. Dr Edwin Borman; European Union of Medical Specialists*

The UEMS represents the largest number of medical specialists. Its main purpose at the beginning was the free movement of professionals; however, it goes far beyond now. UEMS could contribute to ERNs in several ways through the harmonisation of the highest level of specialist training and the medical care provided for patients.

The potential for collaborating with ERNs would be in the areas of patient care, training and research. This would include pooling of knowledge and competence; highly specialised and complex procedures; quality benchmark and improvement; and concentration and mobility of expertise.

One example of this kind of collaboration is the current e-platform to support the assessment of medical specialists based on harmonised standards and on linking professionals. This network has the aim of improving quality of training and care; enhancing links and contacts between professionals; and exchanging experience and clinical cases.

Another example is the clinical skills centre that focuses on a new technology of simulation. The aim is to provide high-quality training and to ensure quality management. Furthermore, it creates networks to simulate conditions, also for rare and complex conditions, to have a more regular practice. This would be particularly useful for ERNs.

Also, there is no doubt about the potential benefits of networking in the area of rare tumours, paediatrics and neonatology, and gynaecology and obstetrics. In conclusion, the profession supports the ERN initiative and will support and provide expertise to the networks. However, from their point of view, the legal framework is not fully comprehensive yet and it is not clear what should be addressed at a national level and what at a European level. This is critical in order to identify whether it is a bottom-up initiative, a top-down one or maybe a unique example where both merge.

Finally, ERN is an initiative that should focus on complex conditions, not only the rare ones, and it will enhance international co-operation in a way that presently is not delivered.



### *The view of the managers. Ms Marianne Olsson; European Health Management Association*

The EHMA is a network that does not work with only one specific target group. Its aim is to build the capacity and raise the quality of health management in Europe by bringing together research, policy and management communities, by providing an arena with research where healthcare managers, policy makers and researchers can meet. There are several threats related to the establishment of the ERNs. The first relates to the effects ERNs may have on complex adaptive systems, such as healthcare systems. It is of utmost importance that ERNs are closely monitored because it is impossible to predict the influence these networks will have.

Secondly, the positive impact we hope ERNs will bring need to be balanced against the potential adverse effects they may have on the rest of the system.

Thirdly, one needs to keep in mind that clinical results are the effect not just of interventions but of the total process. When we talk about ERNs we need to think about all the parts of the system involved. Finally, the networks may hamper innovation due to the linear constructions of the ERNs, which may lead to closed minded entities.

Finally, studies show that there might be other relations beside volume and better performance, and perhaps a less strong than expected relation between volume and performance. For example there might be a cost threshold or a higher importance of dissemination of healthcare.

Some benefits might be due to better mutual learning, in other words a real EU co-operation with accessible knowledge and the possible advantage of benefits of scale. ERN could create a very connected interrelated network.

Keeping in mind that the dissemination of knowledge within the healthcare system is much more important for the outcomes than volume, the benefits of ERNs could mainly be iterative learning, accessible knowledge and scale effects, if proven by solid evidence.

Functioning ERNs would consist of an ongoing dialogue on results in all parts of the process, an open source knowledge-base, accessible by all. Furthermore, they could play an important role in forming relationships between individuals, teams and organisations and it could be a base for a very constructive system of referrals.

The expert managers' role in an ERN would be to ensure that there is an active participation by all in the network, that this participation is made possible, to keep an eye on the systemic effects, both adverse and positive; and to avoid narrow or local interests getting in the way of best possible care. This is why we need to focus on patient outcomes above all.

In conclusion, this is a very promising initiative, but we need to make sure we develop it as an open network for all to participate.

### *The view of the patients. Ms Nicola Bedlington; European Patients Forum*

Patient organisations' involvement brings a wealth of unique expertise and experience that can help develop better services for patients. Involving patients in all aspects of the implementation of the Cross-Border Healthcare Directive and the ERN is a pre-requisite to ensure that policies and practice are fit for purpose and patients really benefit.

ERNs will bring important benefits, such as tackling the inherent challenges of rarity, which include the small number of patients involved, little expertise and the low number of experts in these areas. Centres of expertise pinpoint expertise and gather existing experience to improve patient care. In addition, networks are key to organise the healthcare pathways at national and EU levels. Centres of expertise can have very different structures and ERNs need to be flexible to integrate these differences.

From a patient perspective, one of the key tools and mechanisms ERNs should include are disease registries with international terminology to support interoperability as part of global data-sharing effort. Also, ERNs should promote the use of lab testing facilities which participate in quality assurance programmes, such as EuroGentest. The development of a mechanism for sharing good practice guidelines for diagnosis and care between Member States would also be very welcomed. Furthermore, training and education tools to raise standards of care and multi-stakeholder evaluation of ERNs, with indicators covering processes, outcomes and impact are also a must. Finally, ERNs should not forget to include a communications infrastructure to ensure visibility and transparency of ERNs, their processes and accessibility, cross-border referral mechanisms to help operate the directive and social security regulations, and of course, they should not forget eHealth and Tele-medicine to support tele-consultation, training and education.

Regarding the implementation of ERNs, at a national level it should be envisaged how to integrate different structures, how to find adequate funding, how to ensure real patient involvement, how to provide comprehensive care and how to promote research. Furthermore, ERN should gather a critical mass of patients to support research and develop best practices.

From a patient's perspective, all rare diseases should be covered by at least one ERN, which focuses on groups of diseases such as rare hematologic diseases, genodermatoses, rare pulmonary diseases, etc. ERNs should deliver and disseminate structured healthcare pathways through a high level of integrated expertise to improve diagnosis and care to the best European standards.

EPPF's vision includes the existence of 20 to 30 ERNs based on the different medical specialities, which should take a very multi-disciplinary approach.

Regarding patient involvement, patient representatives involved in the management of an ERN in a meaningful way, such as membership of steering committees, board and project groups, and at all levels of activity, including governance and evaluation. Moreover, ERNs should promote networking of the patient groups representing the conditions covered and participation of patient organisations should be a prerequisite for an ERN to receive funding. Finally, budget of the ERNs should include funding for patient organisations to allow full participation.

Concerning the ERN horizontal criteria, patients welcome the inclusion of patient centeredness, patient empowerment and informed consent; however, there is an absence of explicit reference to involvement of patients. The EUCERD recommendations were very clear that patient involvement should be an integral part of ERN governance structures and evaluation, which is why patients hope to see this developed at least in the technical guidance supporting implementation.

In conclusion, patients are very much in favour of ERNs since they drove for this legislation. However, it is equally important for patients to be involved at the following stages in order to ensure an effective implementation. Moreover, patients want to be valued as equal partners, since they have unique expertise and experience to offer.

## Main points of discussion and debate

- The overall framework of ERNs is adequate, as it is located at centralised level but allows an organic development. In order to ensure the bottom up approach, patients, professionals and managers need to collaborate. The challenges will be to accredit professionals and create openness and transparency in the system.
- There is knowledge from other areas ERNs can learn from and also projects and actions, such as the European Innovation Partnership, where we have many successful examples of networking and how to integrate technology. There will also be new forms of innovation we cannot identify at this moment, as they will develop over time.
- It is crucial to think out of the box. Disruptive and inclusive thinking from the beginning will be key for ERNs.
- There is diversity in guidelines and developments across Europe. Scientific method will need to be tackled at international and also at national level, particularly in the area of rare diseases.
- Collaboration across borders requires standardisation or harmonisation of medical definitions, which is currently absent. Nomenclature and terminological issues are already on the agenda.
- There are big financial burdens related to ERNs. There needs to be a political discussion on access to healthcare and on sustainability.

[A2: National models, chaired by Dr Natasha Azzopardi Muscat; Public health practice and policy of EUPHA](#)

[Specialised Commissioning Services in the NHS of England. Mr Edmund Jessop; Specialised Commissioning Team, NHS England UK](#)

The NHS spends around 10% of its budget on specialised services. There are two types of network currently in the NHS. The first is a referral network, where hospitals can refer to a specific centre, mainly cancer centres. The second is a peer network, which is probably more similar to an ERN, consisting of a network of equals, discussing, collaborating and informing. The latter refers to highly specialised services and has existed already for more than 25 years.

A key feature of the specialist services network, which should also be applied to ERNs, is that they meet annually and every member of the network should attend these meetings.

During these meetings every member of the network presents their results, that is to say, clinical outcomes. Also, patients' experience should be presented here.

These meetings have a standard agenda. There are benchmarks used to measure centres and presentations of interesting cases for them to learn from each other.

Not only the clinician but the whole team should be present to discuss and learn, including nurses.

Also, the involvement of patient organisations in most of the meetings is one of the aims.

Overall, the main purposes are peer education, peer benchmarking and discussing complexities. Moreover, this kind of centralisation is needed for technological development to ensure a sufficient number of cases.

In conclusion, we should emphasise that these networks need leadership and have frequent mandatory meetings to present results, which are essential for the functioning of the network.

#### *National Specialised Medical Care (NSMC) in Sweden. Mr Lennart Christiansson; National Board of Health and Welfare of Sweden*

The Swedish system is probably the opposite of the UK system, with a small population and big geographical distances. Furthermore, Sweden does not have a centrally organized NHS, but has decentralised counties with a tax-based system.

There is a long history of highly specialised care since the 1960s but it was not until 2007 that legislation tackled the co-ordination of such care on a national level.

Sweden has chosen a system that focuses on centralisation from the point of view of selected diagnosis and intervention. This includes management of rare conditions, complex interventions or multidisciplinary requirements, and costly and advanced equipment for diagnostics and treatment. The key objectives of centralisation are quality assurance, cost effectiveness, and research and development. This needs to be balanced with care criteria to ensure care is available, equal, safe and patient oriented.

Commissioning is a five-year process that starts with the nomination and prioritising procedure. Then a review takes place on whether these areas of clinical service is suitable for a national service. Then there is a call for applicants, which are assessed accordingly and, once licensed, there will be an annual follow-up and an evaluation towards the end of this period.

During the assessment, which is a bit like the licensing accreditation, what is mainly looked into is whether the applicant has the structure, the processes, strategies for running the services, past experiences and general criteria.

Regarding structure, competencies are looked into - such as specific skills, team competencies and availability of resources. Research conditions, such as organisation and strategies, research groups and projects and grants, are also considered.

Concerning the process, it is mainly about assessing the competence strategies, strategies for national co-operation and international collaboration.

Experience, results and development are looked into by assessing experience of clinical caseload and experience, international collaboration, clinical outcomes, research, education and development. Finally, general criteria are assessed, such as knowledge-based care, safe healthcare, patient oriented care, equality of care and availability of care.

Regarding the evaluation process, the patient and family perspective is taken into account. One of the main elements is benchmarking, which is not easy, as stratification of data is a challenge. This benchmark is based on self-assessment, quality registry data, indicators and targets, comparison of outcome data and review by international experts

#### *The Portuguese model of Centres of Reference. Dr. Jorge Penedo; Ministry of Health of Portugal*

Portugal is currently reforming its health system to have a more coherent hospital network. The main aim of the framework was to define the concept of reference centres, establish criteria for them, propose an implementation model with finances, and integrate these centres in national hospital networks and ERNs.

The definition of Portuguese centres of reference include experienced multi-disciplinary and highly qualified teams, highly specialised structures and equipment, healthcare provision according to the highest possible quality criteria and competences in the areas of education, training and research.

The ERNs and reference centres should establish synergies to have economies of scale, efficiency maximisation, cost-effectiveness, best practice dissemination and maximisation of innovative potential in medical science.

The reference centres will be integrated in the Portuguese hospital network, usually in urban areas, with affiliated centres located near the population.

One important concept is the affiliated centre, which is a centre that does not fulfil the conditions and criteria to be officially recognised as a national centre, but possesses the knowledge and expertise in a certain specific area of competences recognised by the Ministry of Health. This centre, based on its range of services, should be connected to centre of reference of the same area of expertise.

Regarding the integration of the national centres of reference into the ERN system, only those fully integrated into the Portuguese system will.

Concerning the process of official recognition of centres of reference, a medical scientific committee will identify major areas of intervention, elaborate a proposal of pathologies and procedures, define ratios of national implementation, elaborate a final proposal of specific criteria and indicators for the pathologies and procedures, propose to the Minister of Health the eventual decision of official recognition of centres, candidate to centre of reference, and elaborate a model that brings about the establishing and functioning of affiliated centres.

This committee will permanently be advised by expert groups. These groups will propose specific criteria and indicators for pathologies and procedures, identify the requirements to be considered, when evaluating the candidate centres and clear up doubts and validate evaluation aspects, whenever requested by the Technical and Evaluation Group.

The main challenges faced by the ministry will be the social and local or regional pressure to create and recognise more centres. Furthermore, adequate financing is a must if this system is to be successful, as well as the avoidance of bureaucratic burdens.

Overall, this is a project of great importance for health systems and all stakeholders involved and it will play a major role in improving healthcare in Portugal and the EU.

## Main points of discussion and debate

- Balancing the inclusiveness and the standards of networks is a challenge that can be bridged with the concept of collaborative centres
- Co-operation will be a must for small countries where there are small number of cases, expertise and experts
- A solid information and referral system should be in place
- Benchmarking is crucial but needs to be refined. This will be a big challenge for the Commission
- Patients' organisations are very involved in all steps in some countries but still need further development in others

### [A3: Networking Experiences \(Network pilots funded by EC\), chaired by Ms Annika Nowak; DG SANCO](#)

#### [The Paediatric Cancer network-Expo-R-Net. Dr Ruth Ladenstein; Expo-R-Net](#)

The special interaction in the academic area has increased the survival rate of cancer. The main aim of this network is to support the improvement of paediatric oncology development in the EU.

One of the major steps was to start integrating European clinic research centres and national centres to create an interaction platform. This should lead to the creation of a consortium of partners and co-operation.

To reduce the current inequalities in survival by improving the quality of the healthcare provided across Europe, in particular European countries with lower healthcare. Also, to link pre-existing reference centres of excellence, seeking mechanisms to facilitate provision of information and knowledge (ICT tools, eHealth) and offer patients cross-border best practice health interventions to patients and families when really indicated.

The objectives focus on information and on definition of the patients' needs, rather than sending patients across borders. Also, the building of a Paediatric Oncology ERN roadmap, the establishment of a Paediatric Oncology tumour board, defining the criteria for a common process for identification and certification, the cross-border dimension of long-term follow-up, and integrating very rare tumours and soft tissue sarcomas into a European reference network.

The project impact focuses on its strategic relevance and innovative contribution. Strategic relevance relates, firstly, to the generation of information and provision of a framework for the PO-ERN to improve standards of care for children and young people with cancer and secondly, to the next level of integration within paediatric oncology. Finally, to the follow-up and advice for childhood cancer survivors allowing integration of outcomes research.

The innovative contributions englobes a clear roadmap to approved expert referral sites and tumour advisory boards for healthcare providers (Paediatric Oncology ERN Network) and secondly, the fostering of eHealth solutions based on interoperability and standardisation to allow well-functioning tumour boards.

#### *The refractory-epilepsy Network. Dr Professor Philippe Ryvlin; E-PILEPSY Network*

The European Parliament has recently voted a written declaration on epilepsy emphasising the major medical and social issues raised by this disease, which affects six million European citizens and which costs 0.2% of European GDP. A large proportion of the epilepsy burden is carried by the 1.8 million European patients whose epilepsy proved drug resistant, and for whom very complex and specialised management, such as epilepsy surgery, is the only hope for a cure. However, there is a huge treatment gap in the field, hampering access to epilepsy surgery for a majority of persons with refractory epilepsy.

The knowledge of patients, professionals, and policy makers about epilepsy surgery is poor, with erroneous views on the risk/benefit balance, cost-effectiveness of surgery, and the appropriate patients' profile. State-of-the-art epilepsy surgery programmes require the collaboration of highly specialised neurology, clinical neurophysiology and neurosurgery departments, which is only available at a restricted number of sites, resulting in the greatest source of inequalities in the management of refractory epilepsy across Europe. Thus, an epilepsy ERN represents a relevant way to address these issues.

The general objectives of E-PILEPSY are, firstly, achieving significant and sustained progress in the quality and harmonisation of healthcare provision delivered to children and adults with refractory epilepsy across Europe. Secondly, reducing inequalities between EU countries in all aspects related to refractory epilepsy (expertise, quality of care, policies). Thirdly, triggering accelerated development of epilepsy surgery, by promoting co-operation between centres in all EU regions. Furthermore, facilitating access to epilepsy surgery by working with all stakeholders (patients, professionals, policymakers). Finally, optimising pre-surgical diagnostic procedures to offer a greater chance of post-operative seizure freedom at reduced risk of surgery-related complication and morbidity.

The exchange of best practice and promotion of harmonisation of care in the management of refractory epilepsy and epilepsy surgery should lead to improving skills of EU professionals involved in this work. This should lead to an increase in patient safety, accuracy of patient selection for epilepsy surgery, and favourable surgical outcome, which would ultimately mean an increased proportion of patients with refractory epilepsy who will be cured of their chronic disease.

The overall strategy of E-PILEPSY is largely based on the development of web-based solutions and eHealth. This includes: 1) providing all relevant information in every EU language regarding refractory epilepsy and its management to patients with epilepsy, their family and primary caregivers through what should become the primary and most reliable e.source of information on epilepsy for European citizens; 2) setting an IT platform shared by all E-PILEPSY expert centres to share knowledge, technologies and practice parameters; 3) setting an electronic database to systematically monitor the clinical activity and outcome of each E-PILEPSY centres.

In conclusion, ERNs should be the way to move forward as they represent a unique opportunity to improve and harmonise standards of care of complex and chronic conditions such as epilepsy, and to boost m-Health and e-Health in EU countries. E-PILEPSY offers great potential to address the needs of 1.8 million EU citizens with refractory epilepsy according to the 2011 written declaration of the EU Parliament.

#### *European Network for Rare and Congenital Anaemias: ENERCA. Dr. Joan- Lluís Vives Corrons; ENERCA*

Patients suffering a rare anaemia are very frequently under or misdiagnosed. They receive inappropriate treatments and might feel anxious and insecure about their condition until they are properly diagnosed. For this reason pooling expertise is crucial.

The first phase of ENERCA (European Network for Rare Congenital Anaemias) started back in October 2002 and ended in April 2004. It was designed to provide patients, their relatives, and care providers with clear and concise information, in their own language, about the different rare and congenital anaemias known so far ([www.enerca.org](http://www.enerca.org)). Also, it provided physicians with a rapid protocol for the identification and diagnosis of rare anaemias.

The second phase of ENERCA ran from September 2005 to August 2008. In addition to congenital anaemias, this second phase also covered all rare causes of anaemia, whether hereditary or acquired.

The third phase started in July 2009 providing even more information and services to health professionals, patients, citizens, stakeholders interested in rare diseases, authorities and pharmaceutical industry managers. The main results were, among others, the establishment of the basis for a future ERN in rare anaemias.

The phase four started in 2013 and will run until 2016, covering the implementation of information and communication tools.

The ENERCA project includes over 90 health professionals from up to 18 European countries, 12 associated partners, 14 collaborating partners and more than 30 affiliated members.

The main policies of ENERCA focus on the increase of efficacy regarding diagnosis, treatment and follow-up of patients and to reduce health inequalities in the diagnosis and prevention of major rare anaemias.

Even though great advances have been achieved in the recent years, facing rare anaemias is still challenging, mainly because of poor implementation of comprehensive data collection and analysis systems. Moreover, clinical care, prevention and diagnosis practices vary widely across countries and great inequalities exist in access to diagnosis and treatment procedures.

e-ENERCA provides an answer to these challenges by the development of three online platforms devoted to data collection and registry, (e-Registry), education and training (e-learning) and telexpertise and telediagnosis (e-Health).

In conclusion, the way forward is the establishment of a consolidated ERN for rare anaemias. To develop long term sustainability for ENERCA it is important to have national recognition of centres of expertise, recognition of the ERN by the European Commission, and national and European economic support.

## Main points of discussion and debate

- The major challenge when creating networks is funding and ICT development, technical requirements, harmonisation of ethical and legal issues, and the inclusion of the patient perspective and patient information.
- Sustainability and the financial dimension of the project need to be tackled. The operational costs and web platform could be financed through the introduction of a fee paid by centres belonging to that network. Another option could be a specific partnership with industry. Finally, the most costly issue will be the maintenance of a database. The only way of financing this would be through the reimbursement process at national level.
- ERNs should be inclusive, integrating all Member States and all stakeholders. In this sense, perhaps some criteria are too restrictive to achieve inclusiveness.
- Cost-effectiveness should be a key criterion to join an ERN.

## Session B: Quality, clinical criteria and performance assessment

### B1 Clinical and professional criteria, chaired by Ms Flaminia Macchia; Director for European Public Affairs, EURORDIS

Enhancing medical professionalism, interdisciplinarity and quality of healthcare through clinical practice guideline development. *Dr Ina Kopp; German Association of the Scientific Medical Societies' Institute of Medical Knowledge-Management (AWMF-IMWi) at Philipps-University, Marburg*

Rare diseases are one of the basic issues on a European level because we have little evidence and guidelines could enhance medical professionalism in dealing with complex and rare diseases.

In Germany, guidelines started being developed because of concern about variation, quality, efficiency, and evidence for effectiveness of interventions in health care. There is also a professional interest in defining current optimal practice in an era of cost containment, with rapid expansion of medical knowledge and a need for decision aids (not standards) for healthcare professionals and patients in the individual encounter.

In Germany the situation is a little different than in many other countries because ownership and responsibility lie with the profession, so guidelines are developed by scientific medical societies.

An important issue to keep in mind is the conditions that need to be fulfilled in order to call a guideline evidence-based, such as implementation on evidence-based strategies, audits, and professional peer review.

In conclusion, there should not be a European guideline to be transferred to the different countries. Instead, we should have a look at how the different countries were successful in improving quality in their local networks, learning from them, distilling the key contents from them and then plan for a European concept which could then be adopted by the Member States.

However, we should accept that there would still be some variation due to cultural, legal and ethical differences between the Member States.

The concept would be national guidelines and evidence profiles as a basis for European consensus on key points. Also, we should think about having an EU Network of Scientific Medical Societies to guarantee multi-disciplinary work. Finally, we should think about an EU Network of Reference Centres and of Registries, which will collect the data to allow evaluation.

*Establishment of clinical criteria: Best Practices, clinical guidelines and patient pathways. Dr Judith Richardson; Clinical Pathways NICE; United Kingdom*

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

Core principles of all NICE guidance include comprehensive evidence base, expert input, patient and carer involvement, independent advisory committees, genuine consultation, regular review, open and transparent process and social values and equity considerations.

NICE clinical guidelines recommend the best ways to diagnose, treat and care for people with particular diseases and conditions in the National Health Service (NHS).

They tackle inappropriate variations in clinical practice, persisting use of ineffective treatments, the need to apply established treatments of proven clinical and cost effectiveness, failure to adopt clinically and cost effective new treatments, variations in prescribing policy between one part of the country and another, and the impossibility for clinicians to read and appraise all relevant evidence themselves.

The key principles of NICE guideline development are that it should be useful to the NHS and should be based on best available evidence and Guide Development Group consensus. One very important step is the involvement of the public and patients, who provide very valuable insights through the personal impact of an illness, disease or condition or the experiences of care. Also preferences and values, outcomes people want from treatment and care, the impact of treatment or care on outcome, symptoms, physical and social functioning, quality of life, impact on family, friends and employers; ease of use of a treatment or service; side-effects; the needs of specific groups; challenges to professional or researcher views; and areas needing further research.

The future challenges that can be identified are integration agenda, as healthcare is not provided in isolation. Also, a focus on standards and indicators, multimorbidity, keeping everything up-to-date and reduced funding for healthcare.

*Assessment of the use of EU clinical guidelines in a Network environment (experiences). Dr Marco Pierotti; The Lombardy Cancer Network (ROL); Italy*

Lombardy has an accreditation system through which both public and private providers compete. It was thought that this system would benefit the economy and the patients. One characteristic is the very clear separation between the providers and the purchasers in the public system. Another feature is that more than 50% of cancer patients come from another region because of the attractive conditions the network offers.

The co-ordination of the Regional Oncological Network of Lombardy (ROL) is assigned to a public comprehensive cancer centre (CCC) and there are 22 nodes on the territory, which are the interprovincial departments. The co-ordinator is not a connector, it is more a focus from which innovation is pushed and brought to the patient.

The advantages of the model co-ordinated by the CCC are the appropriateness & quality of care, equity (for every cancer patient, the best diagnosis and care), sustainability (shared infrastructures and technical platforms) and efficiency.

From a regional perspective this network represents a model for clinical governance. It is an innovative, feasible, measurable model, based on networking of services providing health benefits to the patient, such as correct diagnosis, appropriate treatment, continuity of care and rational access to resources.

From a professional perspective, the network is expected to facilitate interprofessional interaction and developing collaboration by formalising patterns of co-operation among stakeholders, sharing good clinical practices, and sharing clinical cases.

ROL promotes consensus initiatives among more than 1,700 professionals in order to develop clinical practice guidelines for all solid tumours.

Another initiative which needs to be emphasised is START, which is an instrument to support physicians in their everyday oncology practice. START focuses on effectiveness. Available options for diagnosis and treatment are elaborated trying to combine objective knowledge and clinical expertise.

Some future challenges for ROL are, firstly, that all patients should be included in the network, secondly, enabling the choice of the most appropriate hospital for each treatment and finally, the accreditation and designation programmes for cancer centres.

## Main points of discussion and debate

- Criteria for patient involvement should be similar to those for professionals (having experience in the field, being affected by the guideline or recommendation, etc.)
- Health literacy and education are key to involve patients
- Clinical guidelines are hard to keep up to date but it is crucial
- The presence of guidelines is as important as the applicability of these, in order to ensure equal access to care across the EU
- The Lombardy guidelines could very easily be replicated in other regions and across the EU
- Cross-cutting domains are areas such as service delivery, guidance on patient experience, mental health
- The key challenges are the evidence base and adapting the methodology while maintaining the rigour
- Absolute musts to make ERNs a reality are financial support, implementability (related to the need to update recommendations, take into account cross-cutting questions), implementation (we need theory driven, barrier oriented, targeted approaches and economic considerations) and the incorporation of the public and patient perspective

### B2. Accreditation, certification and evaluation, chaired by Nathalie Chaze; DG SANCO

#### *Recognition and approval of highly specialised hospital services in Denmark. Ms Stine Jønson; Danish Health and Medicines Authority; Denmark*

The Danish healthcare quality programme which does the accrediting in Denmark has no role in accrediting or certifying the specialised hospital services in Denmark. Its role is to generate continuous and persistent quality development across the entire healthcare sector in a broad sense (not only in hospitals but also in pharmacies, emergency services and primary clinics).

When discussing the ERN in a Danish context, the responsibility for accrediting and certifying, understood as legally recognising and approving specialised hospital services, lies entirely in the hands of the Danish health and medicines authority.

In 2007 there was a restructuring of the public sector (from 15 counties to 5 regions, from 247 to 98 municipalities) towards centralisation and specialisation of healthcare.

This reform left each of the 5 regions responsible for planning their entire health services, operating the public hospitals and contracting the private operators, and one national authority, which approves specialised functions that hospitals have to apply for, recommends basic functions and acts as consultative committee for the regions.

In Denmark there are 36 specialties with a plan for each specialty and 1,100 functions divided into basic (90%) and specialised (10%) functions.

When setting the demands, the criteria taken into account are complexity (skills, multi-disciplinary), rarity and resources. The core criteria are capacity and stability, volume, experience and expertise, collaboration and facilities, and quality and documentation. The secondary criteria are research, development and education, 24-7 service, and geography.

The master plan was implemented in 2011. Since then there have been small adjustments and at the moment the whole plan is being revised.



The centralisation has achieved one centre providing 75 highly specialised functions. However, there are a few functions that are not available in Denmark, for which patients are being sent abroad.

Regarding lessons learned, the difficulties have been the high number of private hospitals that applied at the beginning and the fact that the plan was very ambitious and detailed. On the other hand, the plan is surprisingly robust and well supported by a political structural reform, as well as well organised and with a mature professional environment which uses it a lot. The remaining challenges are the difficulties in monitoring the plan.

#### *The healthcare accreditation model of France. Ms Fabienne Menot; HAS, France*

French National Authority for Health (HAS) is an independent public scientific body with financial autonomy which reports to Parliament and Government on an annual basis. Its mission is mainly to improve the quality and safety of healthcare in a context of continuous medical progress.

The HAS also has the function to advise decision-makers on public funding level and acceptable pricing of health goods and services based on actual added medical value, to provide guidelines for healthcare professionals and to develop disease management for chronic conditions, to accredit healthcare organisations and healthcare professionals, and to inform the professionals, the patients and the public.

The French accreditation programme is mandatory. The primary objective is the improvement in quality and safety of care through the generation of sustained changes in practices and management. It also has the objective of accountability and information of the public and an increasing role in the regulation.

Regarding the HAS standards, there is an accreditation manual to address the hospital's performance in specific areas and specify requirements to ensure that patient care is provided in a safe manner and in a secure environment. Some examples of priority topics are evaluation of clinical practices policy, a quality and security improvement programme, risk management, and patients' needs. Regarding quality indicators, we can find patients' medical records, anaesthetic records, pain management, etc.

The accreditation process starts with the self-assessment of hospitals by an on site survey, after which the decision process takes place. There are five levels of accreditation, consisting of accreditation, accreditation with recommendations, accreditation with reservation, conditional accreditation due to major reservation and non-accreditation. A public report of the decisions is posted on the website.

The strategic directions for the future include tooling up surveyors and redesigning the survey methodology. The other focus is on schedule for assessment, going from a four-yearly mandatory survey to two-yearly reporting.

#### *Accreditation of Hospitals in Poland. Dr Barbara Kutryba; National Centre for Quality Assessment in Health Care (NCQA), Poland*

The NCQA is an agency of the Ministry of health that provides accreditation on a national level. It started in 1994 with education before moving into accreditation.

There are a few links with the French accreditation programme, which started at the same time. However, the French programme became mandatory and this made it grow to the biggest in the world, while the Polish remained voluntary.

Accreditation in Poland, despite being voluntary, is granted by the ministry. The voluntary basis was kept on purpose to avoid having to lower the standards.

Accreditation is granted for three years when compliance is 75% or above, or denied when compliance is below 75%.

A survey done among healthcare managers some years ago showed that what contributes the most to being accredited is leadership. Only 6% of university hospitals are accredited, which gives an idea of how difficult it is to be accredited.

A very important point is that accreditation is the only way of asking about patient safety and quality with healthcare professionals.

The areas that cause most difficulties for the hospitals in complying relate directly to clinical services. Surgery and anaesthesia, quality and patient safety, and patient care have the lowest compliance - areas in which medical professionals are directly involved.

Accreditation Canada is a non-profit organization with over fifty years of experience in standard setting. It gives external assessment across all health sectors and has presence in over 20 countries on 5 continents. It has internationally recognised standards and is characterised also by its international collaboration through ACI, Accreditation Europe, NIAZ, etc.

Accreditation Canada is pretty much the only one providing accreditation for health systems. Their vision is excellence in quality health services for all; their mission is to improve healthcare quality and patient safety by providing the international community with leading edge accreditation, education and advisory services; and their values are excellence, integrity, respect, innovation.

The programme's scope is to integrate multiple theoretical frameworks (self-assessment, peer review, mandatory criteria, etc.), address a variety of settings (state-wide health systems, family group practice, specialised medical and surgical facilities, diagnostic imaging and biomedical laboratories) and varying levels of assessments (horizontal criteria and conditions that should be fulfilled by all healthcare providers and criteria and conditions that may vary depending on the scope of the concrete area of expertise, disease or condition).

They are not content experts but assessment experts and engage with those who have the latest knowledge about standards and best practices.

The required criteria for their healthcare providers include patient safety programme (specific goals, procedures and outcome indicators focusing on key areas), system for reporting/learning from adverse events, patient safety training, hand hygiene policies and audit, safe use of medications, prevention/monitoring of healthcare related infections, safe surgical procedures and safe patient identification. These are also key for the ERNs to address.

Other key high priority criteria for healthcare providers include how patients' rights are respected, sharing of information about complaint procedures, and active evaluation of patient experience.

The Trauma Network Distinction as an Assessment Model for Reference Networks.

In this network there are two levels, one co-ordinates care and the other includes the whole continuum of care. The network tries to address the interactions and the transition of care from pre-hospital until rehab, in order to ensure that clinical outcomes are optimal.

## Main points of discussion and debate

- The Danish example shows that specialisation has helped to improve the overall quality in healthcare services and treatments. Also, it seems that the medical associations are very happy about the centralisation and specialisation. The biggest challenge has been the impossibility of monitoring the new plan that will be implemented in 2016. It is very difficult to know what quality indications they should be looking at
- Accreditation should not be bureaucratic but in order to monitor quality you need some kind of evidence
- Systems that accredit national accreditation systems bring important challenges, such as the language barrier. For example, ISQua requires all documentation to be in English
- The elements that should be part of an accreditation process are communication and information for patients and risk reduction systems to report adverse events, among others. Also, the criteria need to balance structure, process and outcomes
- Involvement of patients in the accreditation process is key, not only at the end of the process but throughout the development, e.g. thorough their participation in advisory committees, in the standard development process, and on the board
- None of the present accreditation systems look at research activities. ERNs would probably not look at this until the stage of evaluation

## CLOSING REMARKS

The concluding remarks were made by Dr Andrzej Rys, Director Health Care Systems, DG SANCO, who thanked all stakeholders involved in the process and gave a special thank you to the Cross-Border Healthcare Team (Unit D2, DG SANCO). There was great enthusiasm among participants and speakers during the conference.

However, there are also critical points that need to be taken into account along the way, such as achieving the right balance between the administrative approach and innovation.

Also, there is still a lot to be done concerning funding and co-operation across borders within the scope of the Directive and we need to be innovative to make this system sustainable.

Furthermore, we need to improve our efforts in involving patients and providing better access to care for patients, which sometimes might not be available in their home country.

Other points discussed were related to the legal framework, technical issues, quality and patient safety, diagnosis, treatment, training for professionals (not only clinicians) and the involvement of managers and payers to make the system work, among others.

There was general agreement that sharing experience and knowledge should be a key priority of ERNs. In this sense, the best practice sharing models that were presented today will be very useful.

Finally, it is of utmost importance that we do not duplicate efforts. This can be done by ensuring that all available tools are known so anyone can make use of them and learn from each other, such as developing standardised tools, registers, patient pathways, IT systems and m-health.

## CONCLUSIONS AND STEPS FORWARD

The main challenges identified for the future of ERNs are sustainability and inclusiveness of ERNs. In the area of sustainability, it is crucial to find a long-term funding mechanism. This could be achieved by combining EU funding sources with national ones, as well as other business models, such as industry partnerships. One proposal to finance the operational costs and web platform was the introduction of a fee paid by centres belonging to that network. However, it was also acknowledged that one of the highest costs would be related to the maintenance of a database, which would probably have to be financed at national level through the healthcare system.

Concerning inclusiveness, ERNs should try to avoid elites and involve all stakeholders in the process, by allowing a certain flexibility and by ensuring a high level of collaboration among participants.

The implementation and establishment procedure of ERNs will also most probably be a challenge, when ensuring compatibility with the criteria laid down in the delegated decision and evaluating providers that want to build up a network.

Other main issues that could be challenging during the implementation of the legal framework may be ICT development, technical requirements, heterogeneity of ethical and legal issues and the inclusion of patient organisations as an integral part of the network. Also, the questions of how to accredit professionals, create openness and transparency in the system, and tackle the diversity of guidelines across Europe, such as the scientific method behind them, should not be forgotten. This also raises the issue of collaboration across borders in the light of the heterogeneity of medical definitions, nomenclature and terminological issues.

In order to bridge some of these challenges, it is crucial to make use of lessons learned by national networks and pilot networks, as they provide proof of concept, evidence and important experience.

In conclusion, despite the many challenges ERNs will face, it seems clear that this system will enhance international co-operation in a way that presently is not delivered. Furthermore, ERNs should be the way to move forward as they represent a unique opportunity to improve and harmonise the standard of care for complex and chronic conditions and to boost m-Health and e-Health in EU countries.

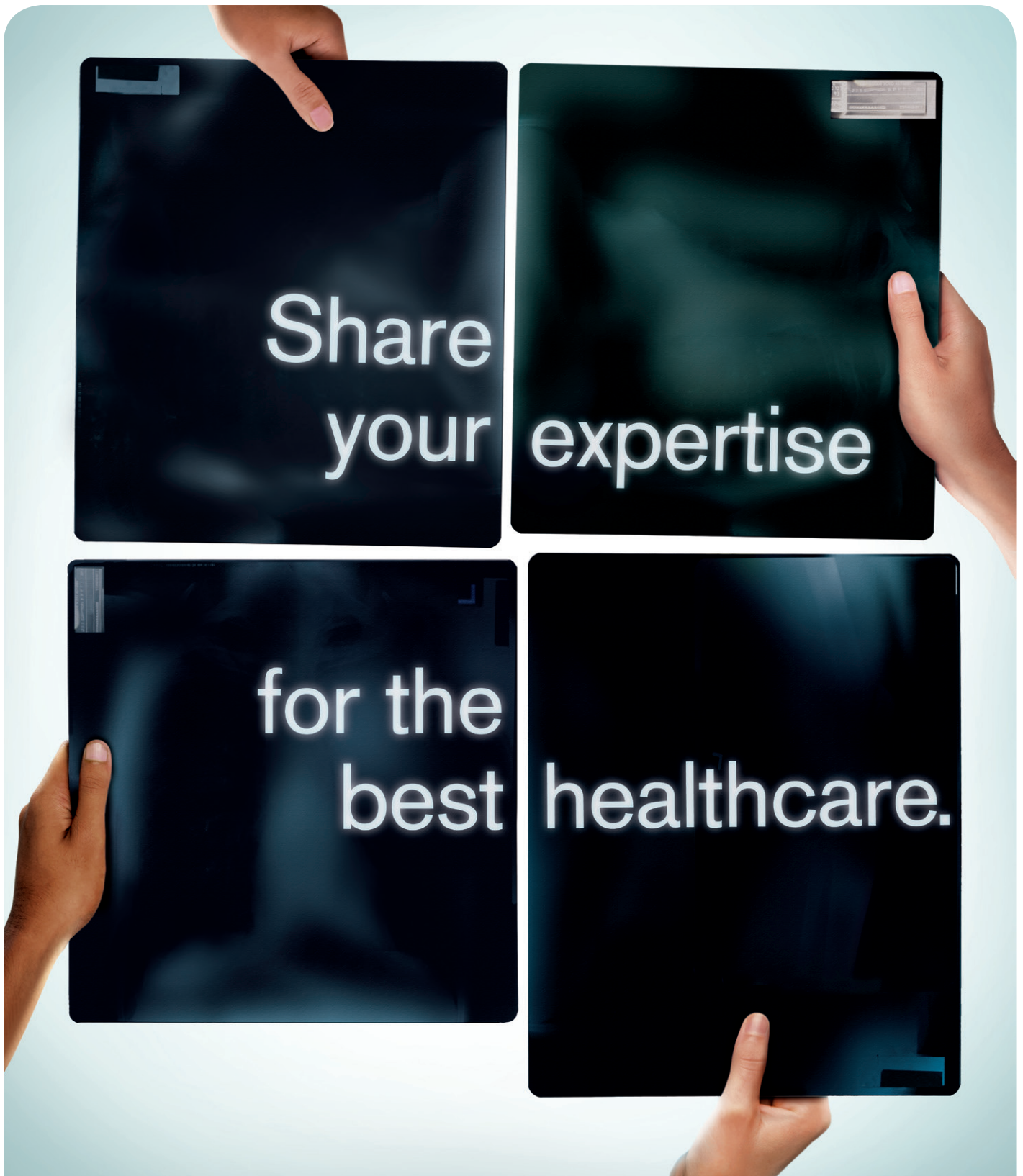
In terms of milestones and steps forward, after the entry into force of the ERN legal acts in May 2014, the call for the assessment manual took place in July 2014, the call for selection of independent bodies will be made in the fourth quarter of 2014, the call for networks in the fourth quarter of 2015, and the networks will be established in the second quarter of 2016.

All involved stakeholders are requested to prepare the network proposals during 2014-2015 by identifying the clusters of diseases (ERN scope), qualified healthcare providers and informal networks and by establishing synergies. Then, during 2015 the Commission will produce guidelines and technical documents for the network proposals.

## ACKNOWLEDGEMENTS

Under supervision of the policy officers of the unit of Healthcare systems (D2) of DG SANCO, the following people wrote this report:

Ananda Plate and Wilco Tilburgs



Imagine if the **best specialists** from across Europe could join their efforts to tackle **complex or rare medical conditions** that require **highly specialised healthcare** and a concentration of knowledge and resources.

That's the purpose of **the European Reference Networks** and it's becoming a reality.

Share and enhance your expertise. Talk with your colleagues. **Be ready to prepare a proposal and join a network.** The European Commission will launch a **call for Networks in 2015.**

More information at [ec.europa.eu/join-ern](http://ec.europa.eu/join-ern)



European  
Reference  
Networks

An initiative of the

