

Board of Member States

ERN implementation strategies

January 2016

As a result of discussions at the Board of Member States (BoMS) meeting in Lisbon on 7 October 2015, the BoMS set up a Strategy Working Group to further consider the wider context for the aims and objectives of European Reference Network (ERN). Following initial discussions, focus areas were identified as the framework for a number of strategic themes that need to be addressed when establishing ERNs. Each theme will require a set of strategic recommendations or directions to support and facilitate prospective ERN applications. It is to be stressed that ERNs are based on the voluntary participation of their members. Equality and mutual recognition of all Member States is of utmost importance. The BoMS has the delegated authority to develop criteria and conditions that any network must meet for its approval by the Board. Such criteria must respect the freedom of each Member State (MS) to decide what type of healthcare providers are considered appropriate for national endorsement, ensure its processes are transparent and its objectives are clearly defined.

How to address fragmentation and too limited scope of the network proposals

The Board is, in accordance with the relevant Act, competent to decide on which type of ERNs to approve and on which criteria that should apply. Hence, the BoMs will decide on the approval of the positively assessed ERN proposals based on their level of maturity, relevance and expected added value for healthcare in Europe.

Information on networks in relation to positive and negative assessments should be shared with the BoMS, since such aggregated knowledge will contribute to the development of the ERN process. Access to details from the positive and negative reports will be guaranteed to the health care providers and to the respective BoMS national representative during the endorsement process.

The added value for EU citizens should be based on the pathologies that constitute the scope of the ERN and which healthcare services the ERN will provide, including a comprehensive and detailed portfolio of the healthcare, educational and research activities that the ERN and the centres within the network provide. This information will provide evidence for the identification of those ERNs that provide added value for European citizens, through the delivery of access to expert advice for patients through comprehensive and inclusive networking. This is what networks must reflect and prioritise in relation to the interests of ad hoc or research pressure groups. ERN must improve the access to diagnosis, treatment and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and should also be focal points for medical training and research, information dissemination and evaluation. Therefore, any network that submits an ERN application should clearly show how the network will deliver benefit to the whole patient care pathway and the connections with the patients' healthcare centres in the country of origin that will facilitate cross-border healthcare.

Information for thematic grouping and the prioritisation of networks should be issued by the BoMS as earliest as possible. As an essential first step, the BoMS must make a decision on the scope of networks to be approved, the area of interest each network will cover and how the networks will operate both as a single entity and as groupings focused on specific disease areas.

For the second step, the BoMS should analyse all suggestions to be considered in the approval process. As it will not be feasible to establish all thematic networks at once due the different level of maturity of the current pilot projects and possible proposals, further calls should be launched in due time, as provided in the legal base, so that all potential thematic groups of rare and low prevalence and complex diseases and conditions would have the opportunity to be covered by a Network. The tentative date for further calls should be communicated in the near future.

The BoMS will need to agree on a statement that should be communicated in a clear and transparent way. The agreed statement on priorities, thematic areas and strategic values should be published on the official ERN website to enable potentially interested centres to find partners in similar fields. Network proposals must adhere to the agreed groupings within a thematic network. However, it is important to emphasise that individual healthcare providers will not always need to align precisely with all themes or have expertise in all areas within a particular ERN. There must be consensus among MS on this issue from the outset. If not, it will be difficult to deal with fragmentation and avoid uncontrolled expansion of new and existing networks.

How to support collaboration and promote cooperation between similar interested groups in a common thematic field

The BoMS needs to bring clarity to its thinking on a broad approach to establishing ERN in order to have confidence in being able to make the case for its decisions and explain the reasons behind them. The benefits of cooperation and collaboration among and within networks should be promoted to well established and functioning networks and healthcare providers wishing to join networks. This should be emphasised in discussions with clinical specialists and others to gain understanding and acceptance of the BoMS position on the themes of networks and their groupings.

The number of networks should be limited to one per thematic group

As set out in the Directive, ERN shall fulfil at least three of the eight objectives stated. Therefore, the BoMS should foster collaboration among centres that can facilitate access to expert opinion in diseases that require high specialisation and technology or have low prevalence. This should be a fundamental principle that underpins the establishment of broad, thematic networks covering a wide range of highly specialised healthcare services for the same or similar group of diseases limiting the number of networks to one per thematic group.

Any procedures should fully utilise the opportunities that the establishment of ERN present to access, use and build upon the considerable experience and skills found in existing networks. There needs to be a level playing field for all those who wish to apply to establish or join a network. The process must be equal, fair and robust in order to encourage applications from all levels of interest. Any internal validation process must avoid inadvertently giving built-in advantage or disadvantage to application.

Healthcare providers should be able to apply to join established networks at any time

Regarding applications for Membership to an approved ERN, it is important that healthcare providers can apply to join established networks at any time in order to meet the Directive's vision of a continued development of ERNs. Administrative procedures for the handling of applications to join existing networks will need to be developed that support this position and clear guidance issued on the process timetable. New members joining an existing network must meet the same conditions applied to existing members as provided in the delegated and implementing decisions

on ERN. Information on the progress and activities of networks and their affiliated¹ partners should be reported back to the BoMS.

How to assure the connection of member states where there is no centre of expertise to the established ERN in a thematic field.

For the sake of inclusivity each ERN must indicate the entrance pathways for the affiliation of centres others than the approved members of the Network

Network proposals must describe pathways of how affiliated partners others than the approved members of the Network can interact, participate and contribute to the networks. The procedures by which affiliated partners access entrance pathways and engage with networks must be clearly defined in the affiliation rules for networks. The operational models underpinning engagement with affiliated partners, e.g. 'hub and spoke' models, must be clearly described and show how they support interaction and deliver wider geographical and thematic spread.

ERN applicants will be encouraged to liaise with National authorities, where appropriate, to identify a list of potential affiliated partners, for collaboration with the network from the outset. However, for all potential affiliated partners (those identified before the ERN approval or those that will come up after the ERN approval) the affiliation process will take place only after the approval of the ERN by the Board and following the formal designation of each of the affiliated partners by its national authorities. The process for the development of networks will also include the enrolment of affiliated partners as well as of new full members at later stages.

Evaluation of affiliated partners is a matter of national designation. It will be very important that the BoMS agrees a minimum set of criteria that, used at national level, would give the affiliated partners a common ground and homogeneity. The technical requirements should be made integral to the rules of the network and be as robust as those applied to network members. There needs to be a fair degree of flexibility allowed on how affiliated partners can interact with different ERNs.

The outputs, knowledge and skills of each ERN must be accessible to all authorised national healthcare providers in all member states

Modes of interaction will depend on a number of factors including the scope (e.g. whether an ERN member is more healthcare services or research oriented) and the breadth of the thematic field. Designating a national coordination hub could be promoted as a mechanism that enables MS to collaborate with those ERNs in which they do not have a healthcare provider as a member. This possibility is open to all MS as provided in the implementing decision on ERN.

The BoMS should be very explicit in the requirement for all networks to be open to potential affiliated partners and that procedures² must be agreed to facilitate their involvement in the development of clinical guidelines, research, training activities, registration of data in common registries and in clinical trials. In information made available to networks, the BoMS should set out how the participation of affiliated partners would constitute an added value to the work of the ERN and realising patient benefit. This contribution could be recognised in shared research, grants and publications, in shared educational activities or in exchange programmes for clinical staff.

How to indicate the priorities, thematic areas or strategic value the MS would like to promote.

¹ Affiliated partners = Associated national centres; Collaborative national centres; National coordination hubs

This objective requires some careful consideration that takes into account the economic climate across Europe, current mechanisms for sharing information and experience, as well as national and European frameworks for access to diagnosis, treatment and healthcare.

Patient inputs on the suitability of networks and their involvement in the approval decision process, as established in the rules of procedures of the Board, should be considered. This would help to reinforce the credibility and value of the decisions taken. According to national preferences, patient representatives' participation as observers in the on-site audits may be an option. The BoMS might decide to consult patient associations in this or any other part of the process. Approved networks should include in their periodic evaluation plan the procedure to evaluate the experience of patients and patients' healthcare centres in the country of origin.

Member states should be invited to communicate their lists of priorities, thematic areas and strategic values.

As part of its decision making process the BoMS should seek the opinion of MS, healthcare providers, already operating pilot networks, professional bodies and the R & D community. Proposals informed by the evidence provided by these discussions should be shared with national stakeholders and experts in the thematic fields of the respective country via the national representatives on the BoMS.

Effective existing networks will already be engaged at an international level, hence, any strategy should describe how ERN will complement, support and build on existing examples of best practice. The balance between the provision of Highly Specialised Care and thematic areas covering Rare Disease may thereby be addressed. The thematic groupings issued by the Expert Group on Rare Diseases may be used as a guide.

In addition to disease related priorities, identified needs for innovations in medical science and health technologies should be highlighted. The consequences for the mobility of medical work force and the delivery of care across borders are also factors to be considered.

The BoMS should develop a list of recommendations on the member states' priorities

When issuing recommendations, the underlying objective is to facilitate improvements in diagnosis and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise or resources in medical domains or members states where availability is insufficient. The added value of the network should be based on the pathologies that constitute the scope of the ERNs and the range of healthcare services provided by the respective ERN. For the sake of harmonisation, emphasis should be given to the use of Information technology to access expertise and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of complex conditions and rare diseases.

How to establish horizontal structures and unifying criteria that could cross all proposed thematic areas

To cover gaps and reduce overlap, MS and European Commission must evaluate and address long-term transversal and structural issues across networks. This would include development of overarching structures, such as common datasets and the linking of databases or quality registers, bioinformatics, IT and e-Health tools. Depending on the disease, the requirements and preconditions for this would vary greatly, but overall there would be great benefit gained through the high-level setting of standards for data management and flow, improving the quality of data and the results from its interrogation. In addition, it is proposed that specialised laboratory services,

sequencing diagnostic capacities and clinical interpretation support could be developed as a horizontal theme with priority across relevant thematic areas.

Pooling such resources and making clinical expertise and second opinion available could potentially contribute to both increases in quality of care and cost savings for member states. Robust, standardised, cross-referenced data collection is essential to reinforce research and epidemiological surveillance. This should support research and development of new therapies and better insight into the nature of disorders, which should be a key objective for all networks. To encourage the development of quality and safety benchmarks and to help develop and spread best practice, providing training for health professionals within and outside the network is essential. A concept for how to do this should be described by all networks.

Standardisation of IT infrastructure and e-Health tools across the MS and between ERNs is a costly and time-consuming process. Therefore, in order to facilitate data exchange and development of common structures, financial support should be sought for within such mechanisms as Connecting Europe Facility (CEF), Horizon 2020, or similar existing or future initiatives.

Conclusions

- A clear strategy for communications must be agreed that describes the high level purpose of establishing ERN, the areas they will cover and what it is hoped they will deliver.
- In developing processes for the establishment of ERN, the objective of building on existing skills and experience should be clearly explained and evidenced wherever possible.
- The ERN task is to facilitate improvements in the diagnosis, the treatment and the delivery of high-quality, accessible and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of expertise or resources in medical domains. Collaborative working methods should be adopted that promote cooperation between ERN applicants, and the number of networks should be limited to one per thematic group as prioritised by the Board of MS.
- The importance of affiliated partners designated by the MS to ERN and their active engagement with ERN should be stated as a clear objective from the outset. ERN must have transparent rules and strategies to facilitate affiliated partner engagement with their network, and describe how affiliated partners can interact, participate and contribute to the networks they enrol in.
- MS should work with their healthcare providers to support any agreed applications for full membership or affiliated partner status, and engage with their patient representatives when setting out their priorities, thematic areas or strategic values they wish to promote.
- All ERNs must clearly describe and evidence how the use of information and communications technology to access expertise will be applied and how it will support the development, sharing and spread of knowledge and best practice.
- The relevance of ERNs and the expected added value for EU citizens should be based on the diseases that constitute the scope of the ERN and those services that the centres within the ERN will provide, including a comprehensive and detailed portfolio of the healthcare, educational and research activities.

- ERNs should clearly establish how the network will deliver benefit to the whole patient care pathway and the connections with the patients' healthcare centres in the country of origin that will facilitate cross-border healthcare.
- ERN should be open to any healthcare provider that meets the criteria requirements and wish to apply to become a member of the existing network. Any ERN membership application process must support easy access for approved healthcare providers to join an established ERN, within a framework that treats all applicants equally. The criteria to be fulfilled should be the same as those initially required at the creation of the network.