Accreditation of Centre of Expertise

Briefing Note (05.05.19)

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1. Introduction

How do you create expert centres knowing there are 6100 rare diseases. The idea is obviously to try to follow the grouping as done in the ERN's but at the level of expert centres, it seems essential to also capitalize on the expertise some centres have for one or two very specific rare diseases or small subgroups. How can you find the balance between general recommendations and disease-specific ones to really create added value and better quality.
RaDiOrg was been invited by the federal administration responsible for public health to give input on the design of expert centres for rare diseases.

The National Institute of Health and Disability Insurance (NIHDI) asked RaDiOrg about examples in other countries and how they went about it, to organize this. The document at hand is the result of consulting with EURORDIS and in particular with Matt Bolz-Johnson, who has had firsthand experience in this matter, as national commissioner in the U.K. responsible for the designation of National Centres of Expertise for ultra-rare diseases and highly specialised healthcare services. He also lead the project team that developed the winning EC tender for the ERN assessment framework used in the first call for ERN applications.

2. Overview

Accreditation Scheme / Framework can be viewed by clinicians as a 'hurdle' to cross at a single point in time and therefore are seen as administrative burdened with little value to their services and day-to-day work. However, published literature positions healthcare accreditation schemes as 'continuous quality improvement schemes' which over time, year on year, the threshold for maintaining national accreditation increases, thereby requiring the services and hospitals to drive quality improvements to their services year on year.

The EC published a literature review on the different models and their evidence base for healthcare accreditation / licensing.

https://ec.europa.eu/health/sites/health/files/ern/docs/mapping_ern_literature_en.pdf

Developing the national accreditation system as a system of continuous evaluation is essential to make any designation sustainable and reliable in the long run.

3. Process

In the above literature review, it highlights the evidence for developing process for a national or European accreditation process. Key evidence includes:

The act alone of measuring 'something' in the literature is often cited as stimulating quality improvement. However, every 'model' for assessment or accreditation has its strengthens and its weakness, so the literature highlighted that the best approach is to use 'multiple models' e.g.: three different models to triangulate the information being assessed.

The EC used the following model:

i. self-assessment which is peer reviewed by the Network;

ii. documentation review by an independent assessment body, and;

iii. On-site visit using a patient tracker system (to look for evidence to validate the self-assessment and documentation review information.

Summary of the strengthens and weakness of the different models for assessment and accreditation:

Table 1 - Summary of Assessment Methods Ability to assess

Location	Effort/ intensity	Structure	Process	Outcome	
Data					
Routine health system	Remote	+	+	+	+
Service specific	Remote	++	++	++	++
Service Based					
Visit	Local	++	+++	+++	+
Staff Interviews	Local	+++	+	+++	++
Patient Interviews	Local	+++	+	+++	++
Questionnaires					
Service Survey	Remote	+	++	++	+
Staff	Remote	+	++	++	+
Patient	Remote	+	+	+++	++
Case Review					
Medical Record Review	Local	+++	+	+++	+++
2nd Opinion	Remote	++	+	+	+++

Reference: EC literature review on the Assessment Methods for healthcare

4. Examples of Good Practice

The EC also completed a 'Mapping Exercise of EU MS National Accreditation Systems' – please see page 27-85 in the document in the link below. In the appendix, there a summary of each EU MS accreditation system including:

- Denmark site visit report
- France site visit report
- Germany site visit report
- Italy site visit report
- Lithuania site visit report
- **The Netherlands site visit report (must read)**
- Poland site visit report
- **Spain site visit report (must read)**
- **Sweden site visit report (must read)**
- **UK site visit report (must read, p. 79 - 84)**

https://ec.europa.eu/health/sites/health/files/ern/docs/mapping_ern_designation_assessmentpractices_en.pdf

There are two different models for CoE that the above countries have adopted – either the Rare Disease Centres Model or Highly Specialised Healthcare Model (e.g.: high-cost intervention and highly specialised surgery) (e.g.: in Sweden, UK, France, Austria, Spain).

Rare Disease model is to support diagnosis, case management and sign-posting and is included in Denmark, Sweden, Germany. Funding can be either as a block payment for speciality nurses (Sweden) or on a 'payment by results' basis (Germany). The two models are NOT mutually exclusive! In Sweden, they commission both models.

Level of investment that is attached to the national accreditation system is proportionate to the success of the newly appointed CoE in fulfilling their designated duties. In the case of case management of rare diseases, the success of these posts / function is dependant on the time (and funding) they can contribute to the cases and the amount of specialisation.

The UK system was to 'commission' for Rare Diseases, Ultra Rare Disease or Highly Specialised Healthcare Services was on population sizes of 1M people to get the ecomony of scale at a Regional Level for rare diseases OR Nationally for ultra-are e.g.: total national caseload of 250 patients per centre.

The U.K. system of national commission was an extremely successful method of designating expertise and CoE, which was government lead and departed from bottom-up identification of available expertise through an annual application process.

UK National Specialised Commissioning Team (NSCT) has an annual process for applications to be developed by a group of clinicians from different hospitals working together across the UK, to submit an application for national commissioning / funding. The National Team had contracts with the majority of the big hospitals (so had contractual relationships) to provide the different HSS services. E.g for NF2 this was commissioned from four hospitals. Complex NF1 was commissioned through two hospitals etc. The NSCT had Public Health Advisors who engaged with the hospitals experts and managed the initial interest to develop an application for national funding. This managed the number being activity developed in any given year.

The UK NSCT had an advisory committee, of the 'great and the good' from the different Royal Societies etc. and Patient Organisations. The Advisory Group for National Specialised Services (called AGNSS) used to review the list of potential applications and decide on the priority services for development each year. The clinical leads worked together for agreed priority services, to develop an application and we as commissioners supported then and submitted the proposal/application (which included a needs assessment, society impact, costing and patient organisations/representatives opinion, service model, MDT team and evidence-base for service/intervention). Once approved in AGNSS the NSCT developed a 'service specification' for each national service which was then put in the contract with the successful Centre of Expertise. Please see list of highly specialised services (national services) in the below link:

https://www.england.nhs.uk/wp-content/uploads/2017/10/prescribed-specialised-services-manual.pdf

Please see list of service specifications in the UK - *this is really good information:*

https://www.england.nhs.uk/specialised-commissioning-document-library/service-specifications/

Example: *Epidermolysis bullosa service (All Ages) – National Service Specification*

https://www.england.nhs.uk/wp-content/uploads/2018/08/Epidermolysis-bullosa-service-all-ages.pdf

In Germany, the NAMSE process (national accreditation of rare disease centres) has finally trigger some of the 16 Federated States to designate the main hospitals (and fund) for being a rare disease centre. Unlike in Sweden, Germany's insurance agencies are providing additional funding to the hospitals for every rare disease patient they see … this is significant funding. Whilst this has not been completed in all 16 Federated States, it is now progressing across the country. (Please speak with Prof Franz Schaefer, ERKNet Coordinator in Heidelber or Holm Greasser, Rare Neurology ERN in Tubingham)

http://www.europlanproject.eu/DocumentationAttachment/NATIONALPLANS_GERMAN_2013_en.pdf

Sweden have a very mature national accreditation process for Highly Specialised Services (HSS) (surgery and intervention) which includes benchmarking outcomes as part of the criteria for designation. No other country has this type of system. (Please speak with Lennart Christiansson, Medicinalråd at the 'Socialstyrelsen' in Stockholm www.socialstyrelsen.se)

Denmark focues on rare disease centres (not disease specific) but more paediatric units that specialise in diagnosis and not the treatment part of the clinical pathway as this second element is still commissioned in the hospital speciality departments. Sweden have now, in addition to the national commissioning of HSS are also commissioning each of the big hospitals (Gothenburg, Uppsala, Stockholm, etc.) to be a 'rare disease centre'. Specifically, to fund case management and sign-posting for parents and patients to the right clinical expert team, however this is just a few additional sessions of a specialist nurse to do this function.

5. Governance / Oversight

The governance of national accreditation / designation systems takes time and resources. Normally, MS have a national team who coordinate the designation / accreditation process and have an independent advisory group to make decisions e.g.: prioritisation and approval of applications. Most have representation from the 'automatous health boards / regions' like in Spain, Sweden and clinical leadership from professional societies and patient representation (for transparency and good governance).

Patient involvement / opinion is always considered as part of the national application round e.g.: The Netherlands, UK, Sweden etc.

Austria has just developed their national accreditation system. Like in the UK, Spain & Sweden, only centres that have been national designated as a National CoE will be given a letter of support / endorsement for their ERN HCP Full Member application. In Austria, the national accreditation system conducts a very detailed process of application and assessment – including a documentation review and on-site visit. This is time consuming and only approx. 5-8 applications can be processed each year. Last year, this limitation in the MoH's capacity to process the demand for national CoE application, resulted in 43 CoE submitted applications to be an ERN Affiliated Partner, as this was a quick process and less rigorous.

Prof Til Voigtlaender (till.voigtlaender@meduniwien.ac.at) is the Austrian ERN Board of Member States representation and is the best person to speak with about their national accreditation system.

Note: All MS have a national team and advisory board overseeing the national designation process and their capacity to process the volume of application is the 'rate-limiting' factor to the number of CoE that are designated each year. It would be worth speaking to the Dutch lead – *Wendy A.G. van Zelst-Stams, Radboud University Medical Center & The Netherlands ERN BoMS representative wendy.vanzelst-stams@radboudumc.nl or Paul Boon (previous BoMS Rep) ps.boom@minvws.nl* as they lead the Dutch national accreditation process which was able to process more applications in a short period of time (please see the Netherlands Report in the appendix of the follow report: https://ec.europa.eu/health/sites/health/files/ern/docs/mapping_ern_designation_assessmentpractices_en.pdf)

6. Evidence-base & Models

The evidence-base that is the rational for developing National Centre of Expertise is the centralisation of care to a limited number of experts. The evidence is that if two or three experts see the total caseload of people with a rare or ultra-rare disease, this increased their level of knowledge and experience, thereby improving the clinical outcomes of patients (and in turn reducing the cost of healthcare resources as people access the right care and treatment preventing co-morbidities and inappropriate high-cost tests and treatments.

This is a highly political topic with some EU MS successfully implementing (and benefiting from) this approach (e.g.: UK, Sweden, Italy); or other EU MS which have not and probably will not implement this due to the political strength of the hospitals (e.g.: Germany).

In some countries, the have designated national CoE as there is a clear population need, however they have not centralisation of care e.g.: no mandate for local services / hospitals to refer patients to these nationally designated CoE – this is the case for Spain.

The key determinate for recognising a centre or clinical team as a National or European expert is based on the volume of caseload or volume of surgeries / interventions, e.g.: for bone sarcoma, this is minimum of 50 bone sarcoma surgeries in one year (UK criteria) or for Primary Ciliary Dyskinesia, a minimum of 5 positive new diagnosis in a year (ERN-LUNG specific criteria), etc. The EC ERN HCP Member assessment criteria was developed to have 'general criteria' and 'specific criteria'. The general criteria are general to the wider hospital services so if 10 departments in one hospital applied to 10 different ERNs, the evidence / assessment of the general criteria are the same. It is only the specific criteria that are disease specific and

related to different ERNs. The specific criteria are set at a Network level but require each HCP Member applicant to demonstrate they meet the specific criteria threshold for that Network (like with the PCD example in ERN LUNG outlined above).

Specific Criteria is defined at a (ERN) Network level to set the threshold for Membership into the ERN, is not solely focused on caseload volume or number of interventions BUT also included i. facilities and equipment, ii. MDT composition iii. Organisation of care as well as in terms of iv. competency / level of expertise. This information was included in the original ERN application, but the EC have published the activity/volume thresholds on their website.

7. Types of Funding

In the UK, funding was allocated locally to local commissioners through a 'formula' that allocated funding dependent on the needs of local populations e.g.: city vs rural, young populations compared with older populations. Funding was pooled together at a Regional Commissioning from local services, to fund the rare disease services for populations of 1M. National Commission funding was 'top-sliced' from the total NHS budget and didn't go through this process, which enable the contracting of the hospitals to be more stable, year-on-year and in turn gave stability to the clinical teams and workforce, which built stable and sustainable services, leading to better outcome for patients as the clinical teams accumulated their knowledge as they had been stable.

Funding mechanisms is a large topic to explain and I won't attempt to cover this here. It is worth noting that every payment scheme creates a set of behaviours – both good and bad!

Different contracting models balance the incentives of payment and exposure to risk to create the optimum conditions for individual services, as each highly specialised services (surgery) and rare/ultra-rare diseases have different needs. Block contracts, cost & volume and payment by results (pay for activity) all have merits but a PbR contract is not suitable for a ultra-rare disease service where the activity levels can vary from 10 patients one year to 2 patients another. The stability of a block contract for services like this enable the hospital to maintain the clinical team (re budget) and build their clinical competency and safeguard patients access and max outcomes of care… as I have said this is a very important aspect of commissioning and national accreditation e.g.: what is funded in above standard care for high-cost, highly specialised services. But ultimately this is what hospitals and clinicians will look for in the discussions about national accreditation … so this needs more time for discussion and exploring the right and optimal mechanism for Belgium.

8. ERN Assessment Process

Below is the assessment framework developed for the ERN application process.

https://ec.europa.eu/health/ern/assessment_en

This is based on the ERN legal framework:

- Implementing Decision **(the 'How') :** https://ec.europa.eu/health/sites/health/files/ern/docs/ern_implementingdecision_20140310_en.pdf

- Delegated Decision **(the 'What') :** https://ec.europa.eu/health/sites/health/files/ern/docs/ern_delegateddecision_20140310_en.pdf

The EC develop a detailed set of Operational Criteria for ERNs and for their HCP Members. This is based on the Delegated Decision above. *Please see attached documents.*

EU MS adapting the ERN assessment framework and legal framework as their national process:

Country which have transposed the ERN legal framework and application/assessment process at a National level (Greece, Austria, The Netherlands) have adjusted the model for their specific conditions in their respective countries. PLEASE NOTE: the ERN legal framework is a 'destination' to reach and should not be used as the baseline threshold for designating national centres. None of the existing 900 HCP Members (CoE) of the ERNs met the EU ERN legalisation! The self-assessment for HCP Member application was developed so experts could use the following scoring to score if they met the criteria outlined in Annex I & II of the ERN ERN Delegated Decision and the corresponding ERN Operational Criteria:

- '0' (zero) – not met
- '1' (one) – partially met (e.g.: the centre didn't meet the criteria BUT had an action plan in place that demonstrated the centre was taking active steps to become compliant with the criteria
- '2' (two) – full met

The threshold for being approved as an HCP Member in an ERN, was that no criteria was self-assessed as '0' (zero) e.g.: to pass you had to have an action plan in place for anything that was not 'full met' by the centre/hospital.

Each HCP Member application had to be supported by a letter of endorsement by the MS, which recognised that centre as an expert centre under that country's law.