

ANNEX

to the Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States

(adopted on 25 June 2019)

A non-exhaustive list of prioritised potential actions that were considered by the Members of the Working Group to be as relevant for the planning and implementation of sustainable integration processes.

1. Key area of intervention: **National rare disease plans/ strategies and legal framework for ERN integration**
 - Inclusion of ERN Coordinators and/or ERN Members/ Affiliated Partners into policy-making bodies (e.g., those responsible for NP/NS adoption/ implementation/ monitoring) or realise another way to involve their expertise into policy-making.
 - Commitment to engage into ERNs through any possible kind of membership or affiliation.
 - Clear and if necessary legally defined procedures for the endorsement of Centers of Expertise (CoE) for the ERN membership and/or designation of Affiliated Partners to the ERNs.
 - Clear and if necessary legally defined procedures for the identification and designation of national Centers of Expertise.
 - Clear and transparent procedural organization and/ or where possible and appropriate a legal definition of other ERN integration-related procedures and processes, e.g., care pathways, clinical networks, referral systems, interregional collaboration in care pathways, accreditation/ certification/ monitoring of Centers of Expertise/ ERN Members, use of CPMS and patients' data management, adoption/implementation of ERN-developed evidence-based resources for clinical practice, medical education on rare diseases, etc.

2. Key area of intervention: **Patient care pathways**
 - Organization of the national care pathways to ensure CoE/ ERN accessibility with the aim to get timely diagnosis and institute appropriate treatments in rare and complex diseases.
 - Multidisciplinary approach and horizontal integration of services in the Centers of Expertise.
 - Care coordination for patients with rare and low prevalence complex diseases.
 - Monitoring of Centers of Expertise and/or care pathways for constant improvement.
 - Where appropriate, to foster interregional collaboration in care pathways to ensure Centers' of Expertise/ ERN accessibility and diminish unwarranted interregional differences in care provision for rare and complex diseases.
 - Vertical integration of services and transitions of care in care pathways.
 - To reconsider national Clinical Practice Guidelines and Clinical Decision Support Tools for efficient diagnostic pathways that include ERNs.

3. Key area of intervention: **Referral systems to the ERNs**
 - Alignment of national care pathways with ERN referral systems to ensure ERN accessibility according to the needs of MS.
 - To foster national and cross-border IT tools and procedures to ensure safe and GDPR-compliant exchange of patients' data for ERN-related services.
 - Establishment of a national network of ERN Members and/or Affiliated Partners to ensure ERN accessibility according to the needs of MS.
 - Establishment, at national/regional level, of networks of diseases groups covered by ERNs in order to ensure smooth patient access to ERN services if and when necessary.

4. Key area of intervention: **Information on ERNs provided at MS level**
 - Aim at strengthening dissemination of information on ERNs, national care pathways, referral systems and health system organization for rare and complex diseases among medical, nursing and allied health professionals according to the needs of MS.
 - Aim at promoting medical education on rare and complex diseases.
 - Aim at strengthening dissemination of information to and increasing awareness of the general public on ERNs according to the needs of MS.
 - Aim at supporting communication and coordination between the different stakeholders involved in the care provision for rare and complex diseases.

5. Key area of intervention: **Support by Member States (MSs) to ERN Coordinators, Full Members and Affiliated Partners**
 - Support (that may *inter alia* be administrative, financial, organizational, informational) to ensure sustainability of national ERN Members and/or Affiliated Partners.
 - Develop an environment that allows ERN Coordinators and/or ERN Members to accept the support provided by EC.
 - Aim at tackling unnecessary and wasteful spending in the care of rare and complex diseases.
 - Identify and address healthcare provider specific needs to enable efficient participation in ERN activities.

Definitions used in this Annex:

A National Plan or Strategy (NP/NS) can be defined as a set of integrated and comprehensive health and social policy actions for rare diseases (with a previous analysis of needs and resources), to be developed and implemented at national level, and characterised by identified objectives to be achieved within a specified timeframe.

EUROPLAN. Recommendations for the development of National plans for rare diseases. Guidance document. Available at: http://www.euoplanproject.eu/euoplanproject/Resources/docs/2008-2011_2.EuoplanRecommendations.pdf.

Clinical pathway - the definition requires all included:

- Utilize a structured multidisciplinary care plan;
- Channel the translation of guidelines or evidence into local structures;
- Detail the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions' (i.e. the intervention had time frames or criteria-based progression);
- Aim to standardize care for a specific clinical problem, procedure or episode of care in a specific population.

Plishka C, Rotter T, Kinsman L, Hansia MR, Lawal A, Goodridge D, Penz E, Marciniuk DD. Effects of clinical pathways for chronic obstructive pulmonary disease (COPD) on patient, professional and systems outcomes: protocol for a systematic review. Syst Rev. 2016;5(1):135.

Care pathways are a methodology for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period.

European Pathway Association. Available at: <http://e-p-a.org/care-pathways/>.

Wasteful clinical care broadly refers to situations when patients do not receive the right care for reasons that could be avoided, thus – from a system perspective – unnecessarily expending resources to achieve a given outcome.

Operational waste points to situations where health care could be produced using fewer or cheaper resources within the health care system.

OECD (2017), *Tackling Wasteful Spending on Health*, OECD Publishing, Paris. Available at: <http://dx.doi.org/10.1787/9789264266414-en>.

Unwarranted variation is service usage differences among providers and regions that cannot be attributed to differences in patient needs or preferences but to other factors.

European Commission. *Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area. Report of the Expert Panel on effective ways of investing in Health (EXPH)*. Luxembourg: Publications Office of the European Union, 2018. Available at: https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/021_erns_en.pdf.

Care integration can be differentiated according to the system levels it involves:

- **horizontal integration:** links services that are on the same level in the process of healthcare, e.g. general practice and community care;
- **vertical integration:** brings together organisations at different levels of a hierarchical structure under one management umbrella, e.g. primary care and secondary care.

European Commission (2018). *Health system performance assessment – Integrated Care Assessment*. Available at: https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2018_integratedcareassessment_en.pdf.

Transitions of care are a set of actions designed to ensure coordination and continuity. They should be based on a comprehensive care plan and the availability of well-trained practitioners who have current information about the patient's treatment goals, preferences, and health or clinical status. They include logistical arrangements and education of patient and family, as well as coordination among the health professionals involved in the transition.

National Transitions of Care Coalition. Available at: www.ntocc.org.

Care coordination is the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.

McDonald KM, et al. *Care Coordination*. Vol 7 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, editors. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies*. Rockville, MD: Agency for Healthcare Research and Quality. 2007.